

**A NOVEL FOOTWEAR INTERVENTION TO ASSIST IN THE GAIT OF
PATIENTS WITH INTERMITTENT CLAUDICATION**

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Abstract

Peripheral arterial disease is characterised by blocking of the peripheral arteries. A common symptom is intermittent claudication, a cramping pain felt intermittently during activity such as walking. This is due to muscle oxygen demand surpassing the available supply and can significantly reduce mobility and quality of life. One non-invasive treatment option is the use of footwear and orthoses to alter muscle activity and delay the onset of calf pain. The aim of the research in this thesis was to determine the gait characteristics of individuals with intermittent claudication and to assess the effects of footwear and orthotic interventions on their gait.

Three studies were completed. The first compared gait of individuals with intermittent claudication to that of healthy age-matched controls. The second assessed the effectiveness of three rocker soled shoes (with and without an ankle-foot orthosis) in altering lower limb kinetics and muscle activity. The third investigated the effectiveness of the most effective rocker soled shoe intervention (in study two) in increasing mobility during gait and in real world situations.

People with intermittent claudication adopt a slower walking speed and shorter step length and have reduced internal ankle moment and ankle power production during push-off phase of gait. The peak EMG activity of their soleus muscle also appears to be lower than healthy counterparts.

A rocker soled shoe, consisting of three curves blended into one, was found to be the most effective at decreasing the moment, power and muscle activity demand at the ankle during the gait of individuals with intermittent claudication. The findings indicated the potential ability of the shoe to reduce the oxygen demand of the calf, such that it might delay onset of intermittent claudication pain. However, when tested under real world conditions this rocker soled shoe did not significantly delay the onset of pain in people with intermittent claudication during over ground gait, or increase maximum walking distance. Further modifications to the rocker soled design will be required to further reduce oxygen required by the lower limb muscles before a clinically significant delay in intermittent claudication pain can be achieved.

Chapter 1: Introduction

1.1 Introduction

Peripheral Arterial Disease (PAD) is a condition caused by atherosclerosis or stenosis in the peripheral arteries in the human body (Masushita et al, 2017). This stenosis reduces the available blood supply to the limbs and by consequence the peripheral supply of oxygen. When the oxygen supply is lower than the demand it causes cramping and pain of the affected muscles (Masushita et al, 2017). This is known as intermittent claudication (IC) because it exhibits a repeatable pattern whereby the pain comes on with physical activity and ceases with inactivity. This usually occurs at the lower limbs of affected individuals and often after walking only relatively short distances.

PAD is estimated to affect 20 million people in Europe and 8-10 million people in North America, 10% of individuals over 65 years of age and 20% in individuals over 80 years of age (Watson et al., 2006). An estimated 3% of individuals with PAD-IC will require amputation due to insufficient peripheral blood supply but higher percentages of individuals are in need of stabilisation of their symptoms and surgical intervention (Guidon and McGee, 2013). According to Guidon and McGee, the disease has higher chances of causing death than leading to amputation (Guidon and McGee, 2013).

There is high variability in the symptoms experienced by individuals with PAD as well as a high percentage of individuals that may progress from being asymptomatic straight into critical limb ischemia (a severe stage of PAD and IC (Teodorescu et al., 2013)). This often makes development and management of the disease difficult. A targeted treatment approach to PAD and IC has been suggested by the National Health Service (NHS) under National Institute for Health and Care Excellence (NICE) guidance. The patient treatment journey begins with pharmaceutical therapy to help manage limb pain, along with patient education and risk factor modification. Supervised exercise programs have been incorporated as a major form of disease management, with exercise demonstrating a sustained benefit to IC patients for up to three years after the end of a 2.5 month exercise program (Jansen et al., 1991,

Ratliff et al., 2007). A meta-analysis of randomised and non-randomised trials has shown that exercise programs increase walking distance to onset of IC pain by 180% and maximum walking distance by 120%. (Ratliff et al., 2007). However, these programs are not always easily accessible to patients and attendance is highly sensitive to patient motivation. Furthermore, although PAD symptoms usually become stable after initial deterioration, in 20% of patients the condition deteriorates and exercise is insufficient treatment (England et al., 1992, Regensteiner et al., 1993). Invasive surgery, such as angioplasty, stenting and, in most severe cases, bypass surgery, is then usually indicated. However, these invasive procedures carry a risk to the patient, who often already have poor general health, and results may not always be sustained long-term (Creasy et al., 1990, Eberhardt and Coffman, 2003). It is therefore important that non-invasive, patient friendly forms of management are developed to assist in the treatment of PAD-IC.

Since the underlying cause of pain is insufficient blood supply to muscles during physical activity, specifically walking, one possible conservative approach is to use footwear and orthotics to reduce the mechanical workload of the lower limb muscles. Rocker soled shoes have often been considered for the management of disease or as a form of exercise (Chapman et al, 2014, Long et al 2007, Myers et al 2006, Lumeau et al, 2015, Romkes et al, 2006). In patients with peripheral arterial disease and intermittent claudication, rocker soled shoes have been shown to assist in reducing claudication pain and in increasing mobility (Hutchins et al., 2012, Richardson, 1991). However, the research base relating to these effects, both in terms of an explanation and clinical evidence, remains embryonic. For example, neither which features of a rocker soled shoe contribute to a reduction in calf muscle activity, nor the biomechanical reason for this apparent effect, are fully understood. Shoe designs targeted at foot deformity and disease are generally based on a clinical experience and assumptions about footwear features that may be linked to beneficial changes in gait, but these have often not been verified on a biomechanical level.

Furthermore, although many research studies have attempted to characterise different aspects of PAD and IC disease, and potential treatments, literature

reporting kinematic and kinetic differences of PAD-IC gait compared to healthy counterparts is scarce. Many studies attempt to prove the differences in PAD gait using measures of gait economy, frequency response and gait variability (McGrath et al., 2012, Myers et al., 2010, Ayzin Rosoky et al., 2000). Although these can give a good indication of the change present, they fail to identify the specific kinematic and kinetic parameters that might explain these alterations in walking performance.

The aim of the research in this thesis, therefore, is to characterise gait in people with PAD-IC, and use this information to design, test and optimise footwear for these patients based on application of biomechanical concepts.

Chapter 2 of the thesis will explore and critique the literature relevant to PAD-IC gait and footwear interventions. Chapter 3 will identify the gap in previous research that the work in this thesis will contribute to and will define the aims and objectives of the thesis, while chapter 4 will present the methodologies used in the three studies of the thesis (along with reliability studies conducted before data collection).

The study reported in Chapter 5 identifies the differences in gait and muscle activity between individuals with PAD-IC and healthy counterparts. Work in Chapter 6 investigates the effects of rocker soled shoes and ankle foot orthotics on the gait and muscle activity of individuals with PAD-IC. The most effective intervention is identified and then investigated under more real-world environment in Chapter 7. Chapter 8 will present a review of the study findings and their contribution to the research area and will offer recommendations for future research.

It was hypothesised a priori that the strongest criteria for the intervention to be considered effective would be a reduction in internal ankle moment in late stance and reduction in ankle power production in late stance, reduction in peak muscle activity of the tibialis anterior, medial and lateral gastrocnemius and soleus throughout stance. However, the final criteria used to determine the effectiveness of the intervention were formulated and informed by the results of the study in chapter 5. These will be presented in detail and defended in chapter 6.

Chapter 2. Literature Review

2.1 Clinical Background

2.1.1 Pathophysiology of peripheral arterial disease and intermittent claudication

Peripheral arterial disease describes the forming of lipid deposits on the interior walls of the arteries. More specifically due to reasons most strongly associated with smoking and an unhealthy diet, lipids, connective tissue, inflammatory cells, and smooth muscle cells start to build up on the inner surfaces of the arteries (Hernano & Conejero, 2007). With time these deposits form a fibrous cap, the whole protrusion known as plaque, which narrows the circumference of the artery and therefore reduces the amount of blood flowing past the deposit compared to a healthy artery (Hernano & Conejero, 2007). The blood will therefore travel at a lower rate to the limbs past the point of sclerosis (fig 2.1).

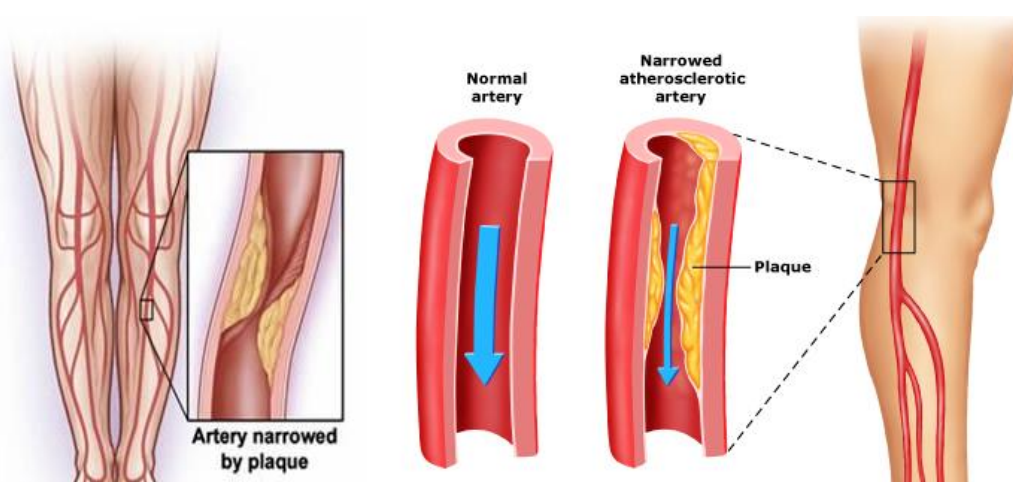


Figure2.1: Depiction of a healthy artery and an artery narrowed by atherosclerotic lesions. (Image from <http://ai3web.com/peripheral-artery-disease/> online)

Intermittent claudication (IC) presents as a common symptom of stenosis in the peripheral circulation. IC in the lower limb, caused by peripheral arterial disease (PAD), is the result of the local oxygen demand surpassing the available supply (Gardner et al, 2009; Gardner et al 2008). More specifically, stenosis of an artery at the lower limb decreases the quantity of blood that flows through the artery distal to the blockage and by consequence the quantity of oxygen and other essential

nutrients that reach the surrounding tissues. when humans engage in any activity which increases the demand for force production by specific muscles, there is an increase in blood flow to the exercising muscles, to supply them with the oxygen and nutrients required to maintain the activity (Joyner & Casey, 2015). In individuals with PAD-IC, because a smaller quantity of blood reaches the muscles within the same timeframe, due to the deposits in the arteries, blood flow will be reduced.

Although skeletal muscle also makes use of anaerobic metabolism, when energy demands increase, during walking or exercise, muscles require a higher supply of oxygen. In healthy individuals an increasing heart rate will pump the blood through the body at a faster pace to cover the demand. In individuals with PAD however, the blockage in the arterial vessels prevents this process. As a consequence, the tissue becomes ischemic (devoid of oxygen) (Gardner et al, 2009; Gardner et al 2008). This manifests as cramping in the limb distal to the stenosis (Gardner et al, 2009; Gardner et al 2008). This pain is known as claudication pain or intermittent claudication.

Prolonged repeated depletion of oxygen has been shown to cause both damage to tissues as well as changes at the level of muscle fibres (England et al., 1992, Regensteiner et al., 1993). More specifically, repeated cycles of ischemia and reperfusion cause an increase in type I muscle fibres within a muscle. These fibres are shorter and require a stronger nerve signal in order to react but are more fatigue resistant compared to type II muscle fibres (England et al., 1992, Regensteiner et al., 1993). The decrease in oxygen supply often also causes distal axonal degeneration of peripheral nerves (Gröne et al, 2014; Weber & Ziegler, 2002). As a consequence, there is poorer signal conduction which causes poorer activation of these muscles. This in turn will cause further muscle atrophy.

As mentioned above, in individuals with PAD-IC the increased demands for oxygen via the blood cannot be fully met. Therefore, any non-invasive intervention used to balance the oxygen supply and demand in these individuals would need to reduce the demand of oxygen at the lower limbs, by reducing the muscle activity, as increasing the supply is not structurally possible without surgery.

2.1.2 Disease prevalence

A population-based study on 7715 subjects (40% men, 60% women) aged ≥ 55 , determined the prevalence of PAD as 19.1% (16.9% - men and 20.5% - women) (Meijer et al., 1998). While men present with the disease to a higher degree than women at younger ages (11.5% compared to 17.1% - ages <70), the incidence in women increases steeply at greater ages (from 11.5% to at <70 to 39.2% at ≥ 85 compared to 27.8% for men) (Diehm et al., 2004). Although disease progression is similar in both sexes, women were found to suffer greater mobility loss and functional impairment than men (McGrae McDermott et al., 2007, McDermott et al., 2011). A higher incidence in African Americans was also identified compared to Caucasians (22.8% vs 13.2%) (Collins et al., 2003). PAD is positively correlated with increased Body Mass Index (BMI) (prevalence ratio (PR) =1.20, 95% CI: 0.94, 1.52) (Ix et al., 2011). However, individuals suffering of PAD are more likely to have a history of unintentional weight loss and therefore lower average BMI, possibly due to smoking and a deteriorating health ((PR: 0.92, 95% confidence interval (CI): 0.85, 1.00) (Ix et al., 2011).

Meijer et al (1998) indicated that within the PAD population only 6.3% report symptoms of IC (8.7% in men, 4.9% in women) signifying a much lower prevalence of the symptom than the disease itself. Prevalence of IC has been shown to rise from approximately 1% at age 30 to approximately 3% at age 55 to 59. From the ages of 60 to 70, a steep increase from 3% to 7% was reported (Meijer et al, 1998). A more recent study however indicates a much higher percentage of individuals of 50% and above that reporting symptoms of IC (Hirsch et al, 2005).

Studies have reported that on average 75% of individuals with IC will experience symptom stabilization or improvement of symptoms without any intervention, despite the progression and aggravation of atherosclerosis (Andreozzi and Martini, 2002). Worsening of symptoms is observed in approximately 25% of individuals with IC, reported mostly during the first year with subsequent deterioration rate of 2-3% annually (Andreozzi and Martini, 2002). According to Dormandy et al. an Ankle Brachial Pressure Index (ABPI) of 0.5 or less at initial diagnosis is a strong predictor of subsequent deterioration along with a history of smoking and/or

diabetes (Dormandy et al., 1989). The ABPI is a ratio of the blood pressure of the arm and that of the brachial artery taken just above the ankle joint (lower calf) while the patient is lying down (Al-Qaisi et al, 2009). Values not associated with PAD-IC range between 0.9 and 1.40 and show that blood pressure and therefore flow is equivalent in the lower limb arteries compared to those of the arm (Al-Qaisi et al, 2009).

Mortality rates of PAD patients have been placed at 30%, 50% and 70% accordingly for five, ten and 15 years of life with the disease and are positively correlated with diabetes, smoking, hypertension, increased white blood cell count, fibrinogen and asymptomatic carotid disease. Decreasing ABPI is also positively correlated with increasing mortality rate (Dormandy et al., 1989).

2.1.3 Risk factors

The main risk factors for PAD and IC, as reported by major large population studies, are smoking and diabetes, followed by hyperhomocysteinemia (elevated levels of circulating the protein homocysteine in the blood because of deficiency of vitamins B6, B12 and folic acid). According to the Framingham study, it is twice as likely that a smoker will develop PAD as coronary artery disease (Kannel and McGee, 1985). It is also twice as likely for individuals suffering from diabetes to develop PAD than healthy counterparts (Kannel and McGee, 1985). Other independent risk factors include hyperlipidemia (high cholesterol) and hypertension (Ness et al, 2000). Any risk factor combined with smoking triples the likelihood of developing PAD (Abela, 2004). Prushik et al (2012) have also identified parent history of IC as a risk factor for presence of IC in offspring.

According to Schmieder and Comerota (2001), risk factors for developing IC include arthritis, radiculopathy, inflammatory processes, spinal stenosis and venous claudication. Risk and contributing factors also include male sex (2-3 times greater chance), aging (increases likelihood with every additional year of life) and smoking (causes abnormal nitric oxide dependent vasodilatation) (Surgery) (Schmieder and Comerota, 2001). Therefore, not all risk factors for IC are related to PAD, a common

example being spinal stenosis. However, PAD is the main direct cause of IC and primary scope of the current research.

2.1.4 Current management of PAD-IC as per NHS-NICE guidelines

High variability in PAD symptoms amongst individuals as well as high percentage of asymptomatic individuals often makes effective treatment of the disease difficult. However, targeted treatment approaches have been advocated by the NHS under NICE guidance (NICE, 2012) (fig 2.2). Patient treatment begins with pharmaceutical therapy, ranging from paracetamol to strong opioids to help treat pain, and aspirin or other anti-coagulants to increase circulation and reduce the chances of intra vessel clot formation. Patients are also educated on the disease and are urged to assist risk factor modification by following a healthy diet and immediately ceasing to smoke.

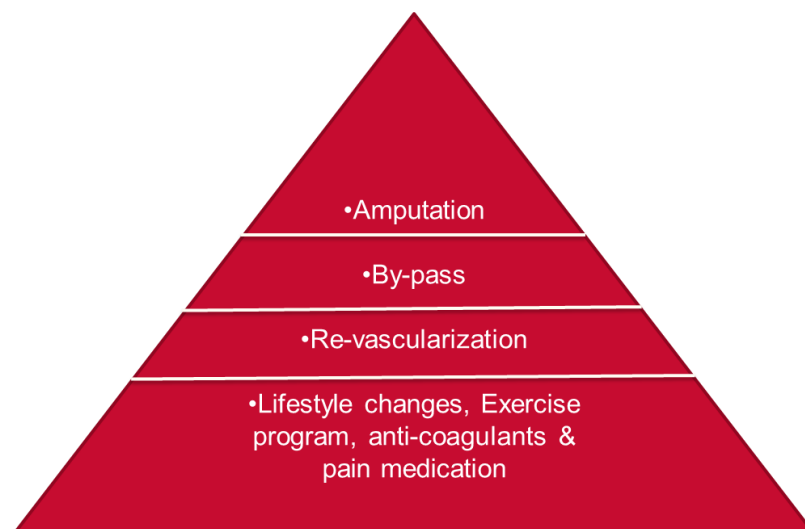


Figure 2.2: Current management of PAD-IC according to NICE guidance

Supervised exercise programs have been used as a form of IC management. The content of the exercise program (often circuit based in structure) differs among organisations but they all include monitored over ground or treadmill walking and calf raise exercises. Both of these types of exercise have been proven to significantly increase walking distance in individuals with IC (Van Schaardenburgh et al, 2017;

McDermott et al, 2017) . Exercise has been shown to increase pain-free walking distance by 180% and maximum walking distance by 120% (Ratliff et al., 2007). Benefits to individuals with IC are sustained up to two years following the end of the exercise programme (Jansen et al., 1991). However, the increase in walking distance because of exercise is not mirrored by a significant increase in ABPI (P.W.K. Ng et al, 2005; Van Schaardenburgh et al, 2017). Furthermore, exercise programs are not always easily accessible to patients and attendance is highly dependent on patient motivation. Furthermore, although PAD symptoms usually become stable after initial deterioration, in 20% the condition deteriorates, and for these individuals exercise is not a sufficient means of treatment. Surgery such as angioplasty, stenting and in the most severe cases bypass, are usually indicated in such cases. Compared to exercise, surgical intervention increases both ABPI and walking time and distance and, provided the surgery is successful, the results are immediate (Creasy et al., 1990). However, these procedures carry a risk to the patient and results may not always be sustained long-term. An estimated 1- 3.3% of patient cases with IC will eventually require amputation due to tissue necrosis as a result of ischemia or indirectly due to non-healing wounds (Norgren et al., 2007).

2.2 Gait in PAD-IC

2.2.1 Introduction

The reduction in circulation, the alterations in local muscle cells and the pain and stiffness experienced during walking inevitably cause alterations to the gait of individuals with PAD-IC. Such alterations present in a consistent pattern within this group of patients and defining them can assist in pinpointing both the localised muscles that are affected by the disease, as well as the compensatory actions made by the body to prevent/reduce pain. Understanding which muscles are most affected by the disease, and at which parts of the gait cycle, as well as the role that the muscles themselves play in PAD-IC gait, are necessary to allow for the design of footwear or orthotic interventions that can specifically unload those muscles at the most appropriate time during gait. However, in order to understand how the gait

of patients with a specific pathology differs from what is considered healthy gait, in a group of equivalent age and cultural background, the gait of the latter must first be analysed. The subsection below will analyse the stages of the gait cycle, referring to the main kinematic and kinetic events. Powers are also cited according to bursts in parentheses, as presented by Winter et al (1995).

2.2.2 Characteristics of normal gait – the gait cycle

A gait cycle is the time period between two consecutive landings of the same foot in the process of normal ambulation. It consists of two phases of double support, where both feet are in contact with the ground, and two phases of single support during which one limb is in swing. When walking at a preferred walking speed, the stance phase of gait takes up approximately 60% of the gait cycle, while the remaining 40% is taken up by swing phase (Perry, 1992).

Hip

The hip joint has a maximum flexion angle of about 30 degrees, which is reached during mid-swing. It then remains flexed at this angle until heel strike. At heel strike the hip is subject to an external flexion moment, which is opposed by an internal extension moment, generated through concentric contraction of the hip extensors, gluteus maximus and hamstrings. This causes power production at the hip (H1) (Winter et al, 1995). Subject to this moment, hip extension occurs and continues until late mid-stance, when the internal extension moment is reduced and an internal flexion moment and power production (H3) (Winter et al, 1995), at heel rise, will take its place. At opposite foot heel strike, the hip reaches full extension (10-20 degrees). Peak hip internal flexion moment also occurs at this approximate time, resulting in the initiation of hip flexion. At toe off the hip continues to flex. This is accomplished by the combined effects of gravity, hip ligament tension and contraction of the rectus femoris and adductor longus muscles (Perry, 1992).

Knee

The knee extends fully near the end of swing phase, so as to properly position the foot for heel strike. After initial contact, due to eccentric contraction of the tibialis

anterior (causing the tibia to rotate forward and the ground reaction force (GRF) to be positioned behind the knee), it begins to flex, an action which is controlled by an eccentric contraction of the quadriceps and a resulting internal knee flexion moment and power absorption (K1) (Winter et al, 1995). As the upper body and hip move forward over the knee, it extends once more, controlled through the eccentric contraction of the quadriceps and power is produced at the joint (K2) (Winter et al, 1995). At opposite foot heel strike the knee has moved into flexion, aided by the position of the GRF which is situated behind the knee joint centre. At this stage the rectus femoris contracts eccentrically, so as to control the speed and extent of flexion and power is absorbed at the joint (K3) (Winter et al, 1995). In late stance and at toe off, the knee remains flexed at half its total flexion angle, assisted by the relatively posterior position of the ground reaction force (GRF). After toe off, hip flexion maintains and increases knee flexion, the latter reaching its peak value during initial swing (Perry, 1992).

Ankle & foot

At heel strike the ankle is approximately at a neutral angle and the foot 90 degrees to the leg. Following initial contact, the ankle plantarflexes, assisting the foot in achieving foot flat. This phase is also known as the first rocker of gait or heel rocker. Eccentric contraction of the tibialis anterior muscle regulates ankle plantarflexion at this stage and causes power absorption at the joint (A1) (Winter et al, 1995). More specifically, the GRF vector is positioned posteriorly to the ankle, generating an external plantarflexion moment that is opposed by an internal dorsiflexion moment generated from the tibialis anterior. As the foot lowers, it pronates, accompanied by internal rotation of the tibia. At opposite foot toe-off the tibia of the foot under examination rotates forward over the foot and the ankle moves into a dorsiflexed position. The GRF moves anteriorly along the base of the foot, causing a reduction in the internal dorsiflexion moment at the ankle. At mid-stance the foot reaches the second rocker or ankle rocker, which presents with the forward rotation of the tibia around the ankle joint. The ankle internal dorsiflexion moment is now changed to a plantarflexion moment due to the eccentric contraction of the

triceps surae. This increases as the GRF vector reaches the forefoot. Contraction of the triceps surae controls the forward rotation of the body, acting against the forward acceleration and torque that tend to tip it forward (Perry, 1992).

In terminal stance, following heel rise, the ankle dorsiflexes again and its angle is kept constant through the work of the triceps surae. The contraction of this muscle group also further reduces tibial motion in the sagittal plane. As the heel rises the metatarsophalangeal (MTP) joints extend and the midfoot everts. This stage is known as the 3rd rocker of gait. The internal dorsiflexion moment at the ankle is increased by the eccentric contraction of the soleus and gastrocnemius muscles. Just before toe off the ankle plantarflexes as a result of the internal plantarflexion moment generated at the triceps surae (medial, lateral gastrocnemius and soleus muscles). This is present to counter-balance the external dorsiflexion moment caused by the anterior position of the GRF in relation to the foot and causes power production at the ankle (A2) (Winter et al, 1995). Finally, at toe off the tibialis anterior takes control of the ankle to return it to a neutral or slightly dorsiflexed position for the duration of swing (Perry, 1992).

2.2.3 Gait in individuals with PAD and IC

A number of studies have researched the alterations in gait brought on by intermittent claudication but not all have focused on gait kinematics and kinetics. Many have investigated the differences in PAD-IC gait using gait economy, frequency response and gait variability measurements (McGrath et al., 2012, Myers et al., 2010, Ayzin Rosoky et al., 2000).

Specifically, Gardner et al (2010) studied the effects of PAD-IC on gait economy. They report that, with aggravation of PAD, when walking in pain, economy is reduced. Amongst the reasons discussed is muscle denervation which impairs optimal motor unit recruitment during a constant load exercise task (Gardner et al., 2010).

McGrath et al (2012) studied ground reaction forces of people with PAD-IC and matched controls, focusing on the frequency instead of the time domain. They

report reduced median frequency which they claim shows more 'sluggish and oscillatory components' (McGrath et al., 2012) within the neuromotor system. Since changes in gait occur before the onset of claudication pain, this suggests that chronic changes within the neuromuscular system have occurred, which is in agreement with Gardner et al (2010). The researchers argue that these may, in part, be due to a change in muscle fibre content to more type I muscle fibres which are slower to react and this is consistent with the lower median frequencies identified in individuals with PAD-IC (McGrath et al., 2012). They also identify reduced bandwidth of movement frequencies which they interpret as 'constrained oscillatory phenomena' (McGrath et al., 2012) in one or more of the limb structures as the patients moved in the anterior – posterior direction (McGrath et al., 2012). Finally, they report a higher frequency content when walking with IC pain, which they interpret as a greater tremor or evidence of instability. This finding both points to and is consistent with the increase in stumbling and falls in the patient group after the onset of claudication (McGrath et al., 2012).

Although these studies can provide evidence that gait is different in individuals with PAD-IC compared to healthy counterparts, they fail to identify any specific kinematic and kinetic patterns which explain this change. These specific differences must be defined if they are to be addressed using footwear and orthotics in a targeted way.

Only seven studies have been identified that report limb kinematics and/or kinetics in individuals with PAD-IC (Celis et al., 2009, Wurdeman et al., 2012, Crowther et al., 2007, Chen et al., 2008, Koutakis et al., 2010b, Gommans et al., 2016, Koutakis et al., 2010a) and compare to healthy counterparts (search terms: intermittent claudication AND gait, peripheral arterial disease, kinematics, kinetics). Data was collected as participants completed a set number of walking trials across lab floors. Patient characteristics and relevant facts of study design can be found in table 2.1 below.

Where an official classification of PAD-IC is offered this is indicated either in the Fontaine or Rutherford scale. The classifications are with respect to the severity of

the disease, as expressed by pain-free walking distance. The tables outlining each classification can be found below (fig 2.3).

Fontaine classification					
Grade	Symptoms				
Stage I	Asymptomatic, incomplete blood vessel obstruction				
Stage II	Mild claudication pain in limb				
Stage IIA	Claudication at a distance > 200 m				
Stage IIB	Claudication at a distance < 200 m				
Stage III	Rest pain, mostly in the feet				
Stage IV	Necrosis and/or gangrene of the limb				

Rutherford classification for acute limb ischemia					
Category	Description/Prognosis	Findings		Doppler signal	
		Sensory loss	Muscle weakness	Arterial	Venous
I. Viable	Not immediately threatened	None	None	Audible	Audible
II. Threatened					
a. Marginally	Salvageable if promptly treated	Minimal (toes) or none	None	Inaudible	Audible
b. Immediately	Salvageable with immediate revascularization	More than toes, associated rest pain	Mild, moderate	Inaudible	Audible
III. Irreversible	Major tissue loss or permanent nerve damage inevitable	Profound, anesthetic	Profound, paralysis	Inaudible	Inaudible

Figure 1.3: Fontaine and Rutherford classifications for PAD-IC. Image by Hardman et al, 2014.

Table 2.1: Characteristics of participants with PAD-IC from studies on kinematic and kinetic changes during pain-free gait with PAD-IC.

Author	Unilateral/ bilateral	Classification of IC	Footwear	Speed(m/s)	Overground/ teadmill
Chen et al 2008	Bilateral	"Moderate arterial occlusive disease"	Not stated	Self- selected 1.14(0.14)	overground
Celis et al 2007	Not stated	Rutherford category 2	Cross Trekks, Payless Shoes, Topeka, Kan	Self- selected N/A	overground
Gommans et al 2016	Both	"Able to walk on treadmill for >1 min"	Barefoot	Self- selected 0.89	treadmill
Crowther et al 2009	Not stated	Not stated	Barefoot	Self- selected 1.08(0.03)	overground

Wurdeman et al 2012	12 Bilateral 6 unilateral	Not stated	Not stated	Control speed matched to PAD speed 1.30	overground
Koutakis et al 2010	Unilateral	Rutherford category 2	Not stated	Self-selected N/A	overground
Koutakis et al 2010	Bilateral	Fontaine stage II and Rutherford grade 1 categories 2 and 3	Not stated	Self-selected 1.14(0.10)	overground

The following are the significant findings of the above studies in temporal-spatial parameters and kinematic and kinetic parameters in each phase of stance with PAD-IC participants during pain-free walking. The literature findings discussed below are also represented in tables 2.2-2.5.

Temporal-spatial

The findings of Crowther et al (2007), Koutakis et al (2010a) and Chen et al (2008) agree that PAD causes a decrease in gait velocity, stride length and cadence. Chen et al (2008) reported no change in step width while Koutakis et al (2010a) identified an increase in step width for individuals with PAD. Chen et al (2008) and Crowther et al (2007) both identified an increase in double support time with the latter also reporting an increase in single support time, ground contact time, swing time and stride time (table 2.2).

Table 2.2: Changes in temporal-spatial parameters of PAD gait compared to healthy age-matched controls.

Temporal-spatial	
Author	Significant results
Chen et al, 2008	Decreased gait velocity, stride length, cadence, increased double support time, no increase in step width
Crowther et al, 2009	Decreased stride length, cadence, speed, increased stride time, ground contact time, swing time, single support, double support
Gommans et al, 2016	Decreased walking speed, cadence and step length
Koutakis et al 2010a	Decreased gait velocity (by 0.14m/s), stride length, step length, cadence, increased step width

Kinematics & Kinetics

Early stance (Initial contact and loading response)

In early stance Chen et al (2008) and Celis et al (2009) both reported increased ankle plantarflexion for individuals with PAD-IC compared to healthy age-matched controls. This contrasts with Gommans et al (2016) who reported a decreased ankle plantarflexion as well as a decrease of 41% of ankle dorsiflexion at initial contact compared to controls. Gommans et al (2016) also reported a reduced ankle range of motion throughout stance, while Celis et al (2009) indicated an increased ankle range of motion compared to controls. As the studies are not in agreement none of their findings can be used confidently in new research on PAD-IC.

Similarly, Chen et al identified a reduction in peak hip flexion (Chen et al., 2008) whereas Crowther et al (2007) identified no significant changes in hip kinematics in

early stance compared to controls. Since neither of the study designs provide reason to be challenged, neither finding can be accepted as more credible.

Of the four aforementioned studies, Celis et al (2009) and Crowther et al (2007) do not mention whether they studied uni-lateral or bi-lateral PAD-IC, whereas Chen et al (2008) report on cases of bi-lateral PAD-IC and Gommans et al (2016) studied a mixture of both. Some of the differences in findings amongst studies may be due to differences in uni- and bi-lateral cases, but no study has as yet investigated this. Therefore, any attributions of effects identified to the unilateral or bilateral form of the disease can be no more than hypothesis and not sufficient to base design of a management aid on.

Gommans et al (2016) and Crowther et al (2007) studied volunteers barefoot, while Chen et al (2008) did not report shoe type and Celis et al (2009) used Cross Trekkers, Payless Shoes, Topeka, Kan shoes. It has been previously proven that walking barefoot or shod, as well as in different styles of footwear, affects gait kinematics and kinetics significantly (Keenan et al., 2011, Wolf et al., 2008, Zhang et al., 2013). This factor, once again, impedes direct comparison and cross referencing among studies.

With regard to moments, Chen et al (2008) and Koutakis et al (2010a) both studied moments in individuals with bi-lateral PAD-IC and healthy controls at individual self-selected speeds. However, their findings differ as Chen et al (2008) identified significant reduction in hip moment in early stance while Koutakis et al (2010a) identified both a significant reduction in hip moment and a significant reduction in knee moment. Footwear was not discussed in either study and this, once again, may be the source of disparities. However, the information available is only enough to theorise on the causes of disparity and provides no direction as to the which study mostly accurately captures PAD-IC gait.

Koutakis et al (2010b) assessed individuals with uni-lateral PAD-IC and compared to healthy controls, at self-selected speeds and their findings only indicated a significant reduction in knee moment in early stance. Although this study may possibly provide an indication of differences in gait kinetics for uni-lateral against

the bi-lateral participants of Chen et al (2008) and Koutakis et al (2010a), a direct comparison between populations is not available in the literature. Therefore, considering the degree to which literature papers disagree with one another it would be unwise to use Koutakis' study (2010b) to draw conclusions as to which disparities may be caused by unilateral versus bilateral disease.

Chen et al (2008), Koutakis et al (2010a) and Koutakis et al (2010b) all reported a reduced internal peak hip extension moment in early stance for individuals with PAD-IC compared to controls. Reduced peak internal knee extension moment was identified in both studies of Koutakis et al (2010a, 2010b), which is noteworthy as one measured uni-lateral and the other bi-lateral PAD-IC. No changes in moments were identified by Wurdeman et al (2012) who tested individuals with PAD-IC and healthy controls at matched speeds. This is an indication that findings in moments may only relate to the effects of walking speed.

In fact, in 6 of the 7 studies (Koutakis et al, 2010a, Koutakis et al, 2010b, Chen et al, 2008, Celis et al 2007, Crowther et al, 2009, Gommans et al, 2016) participants walked at a self-selected speeds. This allowed for the determination of the fact that individuals with PAD-IC walk significantly slower than healthy controls. However, as important as this information is, it masks the true effects of the disease because slower walking speeds (such as those of individuals with PAD-IC) are concurrent with smaller internal moments and powers at the lower limb. Consequently, it cannot be stated with certainty whether and which reductions of moment and power identified by the studies at the lower limb are a direct consequence of the disease itself and which are merely the result of a reduced walking speed. Only Wurdeman et al. (2012) has addressed this issue and a cross referencing of their study findings is necessary if the findings are to inform the design of an intervention for this patient group.

With regard to joint powers, Wurdeman et al (2012), who studied individuals mostly with bi-lateral and some unilateral PAD-IC, Koutakis et al (2010a), who studied people with purely bi-lateral PAD-IC, and Koutakis et al (2010b), who studied uni-lateral, all identified a reduced knee power absorption (K1) (Winter et al, 1995) in early stance for individuals with PAD-IC compared to controls. This is associated

with reduced ability of the knee extensors to control knee flexion during loading response. Koutakis et al (2010a) also report a reduction in hip power generation (H1) (Winter et al, 1995) compared to controls, which implies a reduced ability of the hip extensors to counter the external hip flexion moment caused by the GRF. Once again, owing to the differences in participant disease (uni-lateral/bi-lateral) the lack of accounting for speed by Koutakis et al (2010a) and Koutakis et al (2010b) and the lack of information on footwear, it cannot be stated with certainty which findings are true effects of the disease and whether they apply for the majority of individuals with PAD-IC or specific subsections.

Mid-stance

In mid-stance, once again, there is disagreement amongst studies on the effects of PAD-IC on gait. Specifically, Chen et al (Chen et al., 2008) reported an increase in peak ankle dorsiflexion and Crowther et al (Crowther et al., 2007) a decrease in hip extension but no significant changes in any lower limb kinematics for individuals with PAD-IC compared to controls were reported by Celis et al (2009). The findings of Koutakis et al (2010a), Chen et al (2008) and Koutakis et al (2010b) agree that there were no significant changes in moments during mid-stance, for individuals with PAD-IC compared to controls.

With regard to changes in joint power, both Wurdeman et al (2012) and Koutakis et al (2010a) identified reduced hip power absorption (H2) (Winter et al, 1995) (indicating reduced capacity of the hip flexors to eccentrically control the extension of the limb) and both Koutakis et al (2010a) and Koutakis et al (2010b) identified reduced knee power generation (K2) (Winter et al, 1995), (associated with reduced ability of the quadriceps to counter the external flexion moment from the GRF) but this indicates inconsistencies when considering all three studies together. The reduction in knee extension moment reported by Koutakis et al (2010a), Koutakis et al (2010b) and Chen et al (2008) could be an indicator of reduced quadriceps strength of individuals with PAD-IC compared to controls. However, it could also be a consequence of reduced walking speed of these individuals, since Wurdeman et

al (2012) did not report reduction in any moments. Likewise, the reduced hip power absorption identified (H2) (Winter et al, 1995), may only present in individuals with bi-lateral claudication, since the unilateral study by Koutakis (2010b) did not report this. Once again, conclusions on which effects of the disease to consider true and pertinent to the current research cannot be drawn from the data available.

Late stance (Heel off to toe off)

With regard to changes in kinematics, Gommans et al (2016) and Crowther et al (2007) reported significant findings, with a reduced peak ankle plantarflexion and the latter also identifying reduced hip extension for individuals with PAD-IC compared to controls.

With regard to kinetics, both Koutakis et al (2010b) and Koutakis et al (2010a) identified a reduction in peak internal plantarflexion moment in late stance, with the later study (which tested individuals with bi-lateral PAD-IC) also reporting a reduction in peak internal hip flexion moment compared to controls. Whether the additional result in the latter study is due to participants being bi-lateral or due to a more indicative sample of participants cannot be concluded safely.

With regard to changes in joint power Wurdeman et al (2012), Koutakis et al (2010a) and Koutakis et al (2010b) all reported a reduction in peak ankle power generation (A2) (Winter et al, 1995), which indicates that the triceps surae are less able to concentrically contract and produce normal push-off force. Wurdeman et al (2012) and Koutakis et al (2010a) also identified a reduction in knee power absorption (K3) (Winter et al, 1995), which indicates a reduced ability of the rectus femoris to control knee flexion. This again may signify that individuals with PAD-IC with bi-lateral claudication are also affected more proximally at the knee (as potentially at the hip in mid-stance) but the evidence is not enough to support the claim.

Table 2.3: Changes in lower limb joint angles during gait in individuals with PAD compared to healthy age-matched controls.

Angle/ROM				
Author	Early stance	Mid-stance	Late stance/toe off	Controls matched for:
Chen et al, 2008	Decreased peak hip flexion, increased peak ankle plantarflexion	Increased peak ankle dorsiflexion	No significant differences	age, gender and mass matched controls
Crowther et al, 2009	No significant differences	Decreased hip extension	Decreased peak ankle plantarflexion Decreased hip extension	age, bodymass and BMI
Celis et al, 2007	Increased peak ankle plantarflexion, increased ankle ROM	No significant differences	No significant differences	5 controls matched for age and BMI
Gommans et al, 2016	Decreased ankle plantarflexion, 41% reduction in ankle dorsiflexion	No significant differences	45% reduction in ankle plantarflexion	age

Table 2.4: Changes in internal lower limb joint moments during gait in individuals with PAD compared to healthy age-matched controls.

Moments				
Author	Early stance	Mid-stance	Late stance/toe off	Controls matched for:
Chen et al, 2008	Decreased peak hip extension moment	No significant differences	No significant differences	age, gender and mass matched controls
Koutakis et al, 2010b	Decreased knee extension moment	No significant differences	Decreased ankle plantarflexion moment	gender, age, body mass, and height
Koutakis et al, 2010a	Decreased hip extension moment decreased knee extension moment	No significant differences	Decreased ankle plantarflexion moment and reduced hip flexion moment	gender, age, body mass, and height
Wurdeman et al, 2012	No significant differences	No significant differences	No significant differences	age, body mass& height matched speed

Table 2.5: Changes in lower limb joint powers during gait in individuals with PAD compared to healthy age-matched controls.

Power				
Author	Early stance	Mid-stance	Late stance/toe off	Controls matched for:
Wurdeman et al, 2012	Decreased knee power absorption	Decreased hip power absorption	Decreased ankle power generation, decreased knee power absorption	age, body mass& height matched speed
Koutakis et al, 2010b	Decreased knee power absorption	Decreased knee power generation	Decreased ankle power generation	gender, age, body mass, and height
Koutakis et al, 2010a	Decreased knee power absorption, decreased hip power generation	Decreased knee power generation(early mid-stance) decreased hip power absorption	Decreased ankle power generation, decreased knee power absorption	gender, age, body mass, and height

When individuals with PAD-IC walk while they are experiencing IC pain, the kinematic and kinetic effects on gait are increased compared to pain-free walking of the same individuals (table 2.6). However, the current thesis will not investigate the effects of PAD-IC pain on gait. The reason for this is that any footwear and orthotic intervention, designed to manage PAD-IC, would be targeted at gait during a pain-free state as this is the state that the intervention would aim to prolong.

Table 2.6: Changes in temporal-spatial parameters, and lower limb joint angles, moments and powers during gait of individuals with PAD-IC, while in pain, compared to healthy age-matched controls.

Author	Significant results
Celis et al, 2007	Decreased time to max ankle plantarflexion, Increased time to max ankle dorsiflexion, No significant differences between pain-free and pain
Chen et al, 2008	Decreased velocity (by $\sim 0.3\text{m/s}$) Amplification of temporal-spatial parameters from PF to P, increased stance phase, increased double support time and swing phase. P-controls: decreased peak hip extensor moment – early stance, decreased peak ankle plantarflexion moment – late stance
Koutakis et al, 2010a	Decrease in gait velocity (by $\sim 0.19\text{m/s}$) Decreased peak internal ankle dorsiflexion moment early stance, reduced peak internal ankle plantarflexion moment –late stance, reduced peak internal knee extension moment early stance Reduced peak ankle power generation in late stance, reduced peak knee power absorption in early stance and peak knee power generation in mid-stance
Koutakis et al, 2010b	Reduced peak internal ankle plantarflexion moment – late stance, reduced peak internal extension moment – early stance, reduced peak internal hip flexion moment – late stance Reduced peak ankle power absorption in early stance and peak ankle power generation in late stance Reduced peak knee power generation in mid-stance and peak knee power absorption in late stance, reduced peak hip power generation in early stance, reduced peak hip power absorption in mid-stance, reduced peak hip power generation in late stance

EMG

Gommans et al (2016) was the only study to consider electromyographic activity patterns during gait between individuals with PAD-IC and healthy controls. EMG

data was normalised to 100% of the gait cycle using kinematic data from the medial malleolus and averaged peak performance (in millivolts) from 40 gait cycles was calculated with a threshold value of 25% of the mean peak EMG signal during gait. The study findings indicated that for medial gastrocnemius and tibialis anterior, the duration of muscle activity was the same between groups despite individuals with PAD-IC walking an average of 0.39m/s slower than controls. This was also despite having significantly reduced ankle dorsiflexion at initial contact and ankle plantarflexion during push-off (Gommans et al., 2016). Their findings also indicated that claudication pain induced a significant increase in muscle activity for individuals with PAD-IC compared to their pain free walking. However, the relationship of each group's peak muscle activity, as it related to their mean, was not studied. This would offer a good indication of their capacity to produce force.

Such information is offered by Câmara et al (2012) who measured the isokinetic strength of the ankle dorsiflexors and ankle plantarflexors as well as the knee flexors and extensors in individuals with uni-lateral PAD-IC and healthy age-matched controls. Their findings indicated that people with PAD-IC have reduced peak muscle torque in both dorsiflexion and plantarflexion (which is associated with the forces produced mainly by the tibialis anterior and gastrocnemius and soleus respectively) as well as a reduced peak torque in knee flexion (associated with the force produced by the hamstrings). Muscle endurance was also found to be significantly reduced for the ankle dorsiflexors and plantarflexors compared to healthy controls. These findings, in total, indicate that PAD-IC does indeed cause changes to the physiology of the lower limb muscles (mainly those of the calf and shank) which decrease their ability to produce and sustain force. However, it does not provide insight into the activity of separate muscles and their input to torque production or allow to distinguish whether some muscles are more affected than others. Furthermore, it has not been determined if the reduced ability in torque output is sufficient to affect peak muscle activity during gait.

Summary of most pertinent gait data:

By combining the results of the previous studies we can make the following statements about PAD gait compared to healthy age matched controls:

- Individuals with PAD walk slower, with a reduced step length and an increased step width compared to healthy controls.
- They may or may not manifest a drop-foot after initial contact.
- They have increased dorsiflexion during mid-stance and delayed heel rise
- They have decreased internal ankle plantarflexion moment during heel rise as well as decreased ankle power generation.
- They have a reduced peak hip extensor moment and may have a reduced knee extensor moment in early stance.
- There is uncertainty around the significance of hip moments in late stance
- They have reduced knee power absorption in early stance and may have reduced peak hip power absorption as well.
- They potentially have either or both a reduced knee power generation and reduced hip power absorption during mid-stance.
- There is uncertainty as to the significance of power changes at the knee and hip during late stance-heel-off.

Overall, the literature highlight effects of PAD-IC to the lower limbs which indicate reduced ability of the calf muscles, and possibly some reduction of ability of the knee and hip muscles to progress the limb through stance efficiently. However, if an intervention to reduce the amount of muscle force required by these individuals is to be designed, then the above points must first be verified. This is important to ensure that the lower limb joint moments, which relate to the level of lower limb muscle activity and therefore the design of interventions, have been correctly identified.

It is important here to address once more the issue of walking speed, which was self-selected in most studies and which can affect moments. Studies have shown that ankle moments are significantly affected by walking speed. Specifically, Chehab et al (2017) assessed the effect of walking speed on 121 healthy individuals who

walked at 3 speeds: a preferred walking speed (normal: 1.38 ± 0.16 m/s), a slow self-selected speed (0.93 ± 0.17 m/s) and a fast, self-selected, speed (1.83 ± 0.25 m/s). Their findings indicated that increasing the walking speed significantly increases internal ankle plantarflexion moment in late stance. Similarly, they report that reducing the walking speed significantly reduces internal ankle plantarflexion moment in late stance (Chehab et al, 2017). Goldberg and Stanhope, (2013) also identified a significant interaction between walking speed and the moments of the ankle and hip, with a positive trend in moments with increasing walking speed. However, at present, a specific quantifiable association between the two has not been found. In other words, it is not known what percentage of reduction in ankle moment will be caused by a specific percentage reduction in walking speed.

As mentioned in previous sections, the reduction in oxygen demand at the lower limbs can only be accomplished by a corresponding reduction in muscle activity. One of the factors affecting lower limb muscle activity during gait is walking speed, as seen by its interaction with moment, and individuals with PAD-IC have been shown to walk at significantly slower speeds than healthy counterparts (Koutakis et al 2010a, Chen et al, 2008, Crowther et al, 2007, Celis et al, 2009). However, this change, whether it is a chosen adaptation strategy or a consequence of reduced muscle functionality, is not sufficient to prevent claudication (Koutakis et al 2010a, Chen et al, 2008, Crowther et al, 2007, Celis et al, 2009).

A possibly more effective method of altering muscle activity during gait would be by using rocker soled footwear to manipulate the direction of the ground reaction force during gait and the corresponding moments it creates at the ankle which the muscles have to counteract or control. If a pair of rocker soled footwear can reduce the muscle activity required by the calf muscles during gait, it will by consequence reduce the oxygen demand by those muscles and therefore the amount of blood required to reach the muscles. Therefore, the rate of blood flow to the muscles may then be sufficient to prevent or delay claudication of those muscles during gait.

2.3 Rocker soled shoes as a means of assisting PAD-IC patients in increasing their ambulation levels /Rocker soled shoes for PAD IC

2.3.1 Introduction

It has been suggested that rocker soled shoes may provide a means of conservatively managing intermittent claudication by reducing the amount of activity required from the calf muscles (Hutchins et al., 2012). Rocker soled shoes have a sole which is modified from the standard oxford style or athletic shoe sole to include an angled and/or curved surface (fig 2.4).

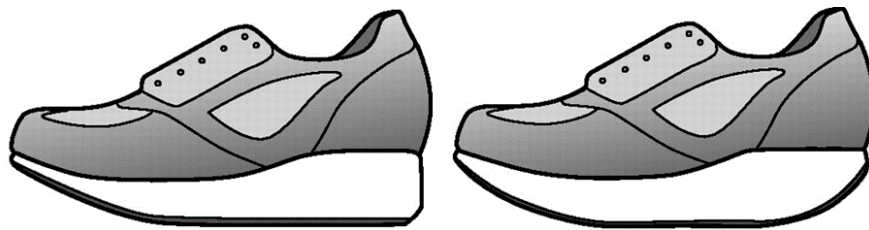


Figure 2.4: Examples of single angled and curved rocker sole shoe. Image from Hospital for Special surgery online resource (Surgery) (date accessed 20/06/2017)

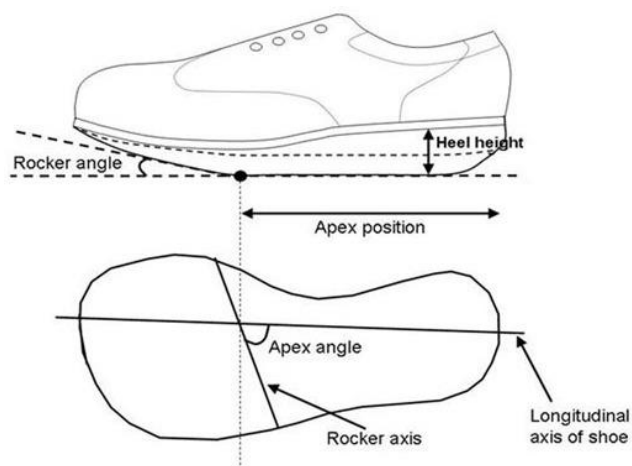


Figure 2.5: Depiction of important design features of a rocker sole shoe. Image by Chapman et al, 2013.

In the past these have been used to reduce ankle or foot joint motion (Rosenfield and Trepman, 2000, Trepman and Yeo, 1995) (i.e in cases of foot fractures or painful joints), to restore or replace motion (MARZANO, 2002) (i.e in cases of ankle arthrodesis, partial foot amputation) to reduce plantar pressures (Chapman et al., 2013, Brown et al., 2004)(for individuals with diabetes) to increase lower limb muscle activity for exercise purposes (Romkes et al., 2006, Sacco et al., 2012) and most recently to reduce muscle activity for disease (Hutchins et al, 2012). There have been many types of rocker soled shoe designed in the past to accommodate different needs. All rocker soled shoes have at least one apex (the point after which the foot is rolled or tips forward by the shoe) but can have more. When designing or describing a rocker soled shoe, the features that must be determined are, whether the rocker is an angled or curved rocker, the number and positions of the rockers (curves) and therefore apexes along the length of the shoe, the angle of the rocker(s) to the medial-lateral axis of the foot and the angle of the rocker to the ground (fig 2.5 by Chapman et al, 2013).

The use of mass produced footwear as a means of managing intermittent claudication would be a relatively cost-effective and convenient way to manage the disease. However, this possibility has not been adequately researched, in that only two studies have focused their shoe design on individuals with PAD-IC and attempted to extend their pain free walking distance by reducing the effort of calf the muscles (Hutchins et al., 2012, Richardson, 1991).

If rocker soles are to be considered as a management aid for PAD-IC, the aim of their use must first be defined. In light of the most probable abnormalities in PAD-IC gait, a rocker soled shoe could serve to manage IC symptoms and correct gait abnormalities by:

- Reducing the external moments and powers at the ankle required for heel rise and toe off
- Reducing the activity required by the gastrocnemius, soleus and tibialis anterior muscles during stance so as to reduce the oxygen required by them during gait, which would bring the oxygen demand closer to the available

supply. This would allow individuals with PAD-IC to walk longer distances without pain.

- Correcting the possible drop-foot in early stance
- Reducing the rate of progression of the tibia over the ankle during mid-stance
- Avoiding increasing external, and thereby internal demand moments and powers at the knee or hip which could place greater demand for force production on the muscles and thereby oxygen, which could lead to IC.

It is possible that shoes that have been designed for a different patient group and purpose, which have features that are known to affect ankle moment and/or muscle activity, can also prove beneficial for individuals with PAD-IC. These might be proven to reduce moments and powers at the lower limb during stance and/or reduce the activity required by the calf muscles.

Whilst there are a number of published studies on rocker soled shoes, there is poor consistency in the specific rocker designs studied as well as in the shoe features and outcome measures used (Chapman et al., 2013, Albright and Woodhull-Smith, 2009, Stewart et al., 2007, Brown et al., 2004, Kavros et al., 2011, Horsak and Baca, 2013, Sousa et al., 2012, Sacco et al., 2012, Stewart et al., 2007, Myers et al., 2006, Peterson et al., 1985, Long et al., 2007). These quite reasonably vary due to the target population and aim of each study but this limits the transferability to the PAD-IC context. Furthermore, the description of the shoe design is not always adequate for the design to be reproducible and thus its mechanism of effect fully understood.

The following is a review of current literature on shoes which have been modified to achieve a specific biomechanical goal that could be related to PAD-IC gait and thus benefit individuals with PAD-IC.

2.3.2 The effect of rocker soled shoes on healthy and diseased gait

Metabolic cost:

Metabolic cost and energy consumption of rocker soles have briefly been investigated in the literature. Hansen and Wang (2011) studied oxygen consumption rate of eleven young, able-bodied persons who walked at self-selected speed with five different pairs of shoes; a control pair and four pairs with uniform hardness (fig 2.6 by Hansen and Wang., 2011). The shoes used are thoroughly described, which allows for comparison with the results of similar studies. All rocker shoes were adapted with a three-inch lift of crepe material. Radii were cut into the three-inch lift of “approximately” (Hansen and Wang., 2011) 25%, 40% and 55% of the leg length, with an apex at 40% of foot length according to data from anthropometric databases. One shoe remained uncut with the three-inch lift and one unmodified shoe without the lift was used as the control shoe. Participants walked in the control shoe, on a previous day, at self-selected speed and were asked to maintain that speed for all shoe conditions.



Figure 2.6: From left: Control shoe, shoe with a 3-inch lift, rocker sole shoe with radius of 55% of leg length, rocker sole shoe with radius at 40% of leg length, rocker sole shoe with radius at 25% of leg length. Image by Hansen and Wang, 2011

Their results show that the rocker shoes with radius at 40% of leg length were the only ones to significantly reduce oxygen consumption rate compared to the control shoe (by 0.8ml of oxygen per minute per kilogram). The shoes with rocker radii at 25% and 55% of leg length significantly reduced oxygen consumption rate compared to the 3-inch lift unmodified shoe (by approximately 0.9ml O₂/min/Kg and 1ml O₂/min/Kg accordingly), but less so than the 40% rocker modification (by

1.2 ml O₂/min/Kg), and not compared to the control shoe. 40% leg length is the approximate position of the knee joint (Hansen and Wang, 2011). In light of the aims of the present thesis, these results likely show that oxygen consumption, and therefore potentially muscle activity, can be altered by the use of rocker soled shoes. This is because reduced oxygen consumption relates to a reduced oxygen demand for force production from the lower limb muscles. This in turn indicates that muscles are required to produce less force to counter the external moments during gait, which equates to lower muscle activity.

The study indicates that when using a single rocker soled shoe, the rocker radius at 40% leg length may be beneficial to individuals with PAD-IC as the reduction in oxygen consumption, and potentially muscle activity, may be sufficient to increase their pain-free walking distance. However, the study was conducted on a treadmill, which alters gait kinematics and kinetics compared to over ground walking (Lee and Hidler, 2008), and only considers energetics, offering no kinematic/kinetic data. Therefore, correlations with other studies should only be made with caution and it is more prudent to consider the 40% leg length radius as a potentially beneficial shoe feature for individuals with PAD-IC rather than study this shoe in particular.

Muscle activity:

Much research has gone into rocker soled shoes that aim to increase lower limb muscle activity or “toning shoes” of varying type (Sacco et al, 2012, Sousa et al., 2012, Buchecker et al., 2012, Sacco et al., 2012, Horsak and Baca, 2013, Turbanski, 2011). These shoes are usually designed with a curved sole which is pliable in different areas and deforms under load (i.e the curve is not used functionally). This in turn is meant to increase the variability in the line of progression of the centre of pressure, thereby reducing balance and causing the lower limb muscles to produce higher forces to control this motion.

MBT footwear have been the subject of several research projects and case studies (fig 2.7, image by Sacco et al, 2012) (Sousa et al., 2012, Buchecker et al., 2012, Sacco et al., 2012). Sousa et al determined that the shoes significantly increase medial



Figure 2.7: Masai Barefoot Technology (MBT) shoe used in the research study by Sacco et al, 2012

gastrocnemius activity when standing compared to standing barefoot, when worn for the first occasion ($p = 0.006$). However, after 8 weeks of use no significant difference was found in medial gastrocnemius muscle activity compared to standing barefoot. Venous return significantly increased with the MBT compared to barefoot standing both in the first occasion of use and after 8 weeks ($p < 0.01$). Buchchecker et al (2012) also identified significant increase ($p = 0.05$) of medial gastrocnemius activity in late stance, in overweight males, walking with the MBT. Sousa et al did not report any significant increase in activity of the tibialis anterior, lateral gastrocnemius, vastus lateralis, biceps femoris or gluteus maximus in 25 females who walked with the shoes for the first time (Sacco et al., 2012). Sacco et al also investigated the effect of walking with MBT shoes on muscle activity of the vastus lateralis, biceps femoris, lateral gastrocnemius, tibialis anterior, and gluteus maximus, on 12 healthy women and determined no significant increases in walking compared to a control shoe.

Other alleged toning shoe designs have also been studied. Horsak and Baca (2013) investigated the effects of Reebok Easytone shoes on gait (fig 2.8, by Horsak and Baca, 2013). The sole of the shoe is embedded with two hemispheres which are centred in the forefoot and heel region of the sole.



Figure 2.8: Reebok Easytone shoes used in the research study by Horsak and Baca, 2013

These cause an increase in postural sway, primarily in the medial-lateral direction, by reducing the contact area with the floor and by obligating the individual wearing them to maintain balance on an unstable surface (due to the pliability of the hemispheres). The study findings show an increase in the first vertical ground reaction force peak and the peak sagittal ankle joint moment in early stance. According to the authors this may cause significantly increased loading on the lower limb joints as a result of co-contraction of muscles. The study also disproves claims of increased instability caused by the shoes. Furthermore, their EMG results showed only a slight increase in activity of the vastus medialis and lateralis, which did not reach statistical significance ($p=0.089$).

Yaodong Gu et al (2014) assessed the effects of shoes imbedded with small stiff semi-circles at the heel and forefoot portion of the plantar surface of the shoe. Twenty-two healthy individuals took part in the experiment, which indicated that the shoes significantly increased peak tibialis anterior, peroneus longus and lateral gastrocnemius during walking. Karimi et al (2016) also reported that standing with unstable rocker footwear significantly increased medial gastrocnemius activity in 10 healthy individuals compared to standing barefoot or with a control shoe.

Burgess and Swinton (2012) investigated the effect of Fitflops(TM) on the lower limb muscle activity of 23 healthy females. Fitflops are promoted as an exercise shoe that tines lower limb muscles. The study investigated the effect of walking with Fitflops on the medial gastrocnemius, biceps femoris, rectus femoris and

gluteus maximus muscles when walking on a treadmill, stair climbing and walking around cones. No significant changes in muscle activity were found compared to completing the tasks barefoot or with regular flip flops.

Comparisons between toning shoes with rockers are also available. Turbanski et al (2011) compared postural control between MBT footwear and Reflex control shoe, but unfortunately the specific design parameters and the specific model of MBT footwear are not reported. The study indicated that the Reflex control shoes significantly increased postural sway in dynamic conditions (moveable platform) when standing on one limb, but not in static standing. The MBT caused no significant effects during either dynamic or static testing conditions (Turbanski et al., 2011). Finally Demura and Demura (2012), investigated changes in vastus tibialis, tibialis anterior, gluteus medius, semitendinosus, gastrocnemius and soleus muscle in 10 healthy individuals when walking with the MBT and the Stretch Walker (SW) (Nosaka, Ltd). They compared these shoes to flat bottomed shoe and did not identify any significant effects.

Irrespective of their effectiveness the rocker soled shoes described above were designed with the aim of increasing lower limb muscle activity. To accomplish this all shoes introduced a degree of instability in either the anterior-posterior or medial-lateral direction by making parts of the shoe sole or the entire shoe sole pliable. A pliable sole will deform under the weight of the body and therefore any specific rocker sole shape will be lost. Consequently, the profile of the rocker sole in itself will not be associated with the any changes in muscle activity. It is rather the pliability of the sole which has the potential to alter muscle activity by introducing unexpected perturbations in balance which the lower limb muscles counteract.

The above findings of a relative increase in muscle activity render “toning shoes” unsuitable for individuals with PAD-IC. However, they provide proof that rocker soled shoes may be able to significantly affect muscle activity and thereby electromyographic (EMG) activity of the lower limb muscles. Therefore, rocker soled shoes that decrease muscle activity, which should provide benefit to individuals with PAD-IC, should also be possible to design. Furthermore, they

highlight that no rocker soled shoe with a pliable sole could benefit individuals with PAD-IC. Therefore, only solid, stiff soles which maintain their curve profile under loads that occur during gait should be considered for the purpose of reducing the activity of lower limb muscles.

Sobhani et al, (2013) investigated the effects of walking and running with a running shoe, adapted to have a rocker profile from the metatarsal heads to the toes. This is the only study which investigates the effects of a rigid and not soft soled rocker soled shoe on muscle activity during gait. The study did not identify any significant reduction in peak triceps surae activity during gait when walking with the rocker soled shoes. This appears in contrast to their finding of reduced peak internal plantar flexion moment. The finding may highlight that a reduction in ankle moment larger than 13% may be required to invoke a corresponding significant reduction in peak triceps surae activity. However, it must be noted that only 13 individuals took part in the study and the authors make the case that power was sufficient for primary outcome measures (kinetics) but limited by sample size for other parameters. The statistical power is not reported in the article but it may be that the power was simply not sufficient to identify a significant reduction in triceps surae muscle activity.

Plantar pressures:

Research has also reported the effects of rocker soled shoes on plantar pressures. Although plantar pressure is not an outcome measure directly connected to managing PAD-IC or increasing pain free walking distance, many individuals with PAD-IC suffer from diabetes as a co-morbidity (Kannel and McGee, 1985). Plantar pressures in cases of diabetic neuropathy are often elevated and higher pressures are a known risk factor for foot ulceration, a common precursor of lower limb amputation (Fawzy et al., 2014, Cavanagh et al., 1993). It is therefore important to consider changes in plantar pressure so that footwear development for patients with PAD-IC can take the needs of this specific group into account.

Several articles have dealt with plantar pressures during standing and walking in rocker soles. Stewart et al (2007) studied pressure distribution in Masai Barefoot Technology shoes (MBT) compared to flat running shoes. A picture of the MBT is available (fig 2.9, by Stewart et al, 2007) but no specifics on the model are given. No information is available about the control shoe other than it being a “flat bottomed sports shoe”.



Figure 2.9: Masai Barefoot Technology shoe (MBT) used by
Stewart et al, 2007

Their findings show that, while standing, the MBT shifted pressure anteriorly under the plantar surface of the foot compared to the flat control shoe. Although the shoes were found to reduce plantar pressures at parts of the foot, they increased pressures at the forefoot, an area with a high risk of ulceration (Waijman and Bus, 2012), and would therefore not be a suitable option for individuals with PAD-IC who also suffer from diabetes

Brown et al (2004) also studied the effects of a negative heel rocker, a double rocker and a toe-only rocker soled shoe on plantar pressures (fig 2.10). They report a reduction in peak pressure under the hallux, under the 1st and 2nd metatarsal heads and under the area between the 3rd and 4th metatarsal heads by all three rocker soled shoes compared to the control shoe. As these areas are associated with a high risk of ulceration in people with diabetes these are positive findings and indicate that rocker soled shoes with a stiff sole should not increase the risk of ulceration in people with PAD-IC who also suffer from diabetes. The stiffness of the sole is essential for the sole to maintain its shape under the weight of the human body. A less stiff sole will would deform under weight, causing variability in the pressure distribution at the plantar surface of the foot and higher risk of high pressures. The toe only rocker and negative heel rocker soled shoes significantly increased peak

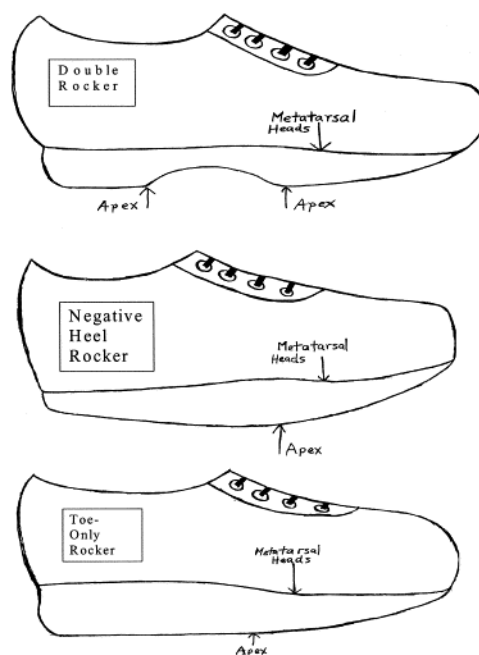


Figure 2.10: Double rocker sole shoe, negative heel rocker sole shoe and toe-only rocker sole shoe used by Brown et al, 2004.

pressure under the fifth metatarsal head, which is a counter indication for using these shoes for individuals with diabetes.

However, such localised increases in pressure may be able to be addressed by insole modifications. In this sense, the double rocker soled shoe, which non-significantly

reduced peak pressure under the 5th metatarsal head, would be a slightly safer intervention for individuals with PAD-IC and diabetes. Peak heel pressures were reduced for all rocker soled shoes compared to the control shoe but the heel is not an area associated with a high risk of ulceration (Waaijman and Bus, 2012). The lack of moment, power and muscle activity outcome measures offer no justification for considering these particular shoes for people with PAD-IC but indicate as to the level of safety of using rocker soled shoes with a stiff sole by people with PAD-IC and diabetes

Chapman et al (2013) studied the effect of specific design parameters of rocker soled shoes on plantar pressures of healthy individuals and individuals with diabetes. Their findings show a significant decrease in pressure under the 2nd to 4th metatarsal heads for all rocker soled shoe conditions, compared to an oxford style control shoe. The first metatarsophalangeal joint was only significantly affected by apex angles at 90° and 100° with a significant reduction in pressure. At the hallux the rocker shoes reduced plantar pressure significantly for smaller sole apex angles (70°-80°), apex positions 50% through 60% and higher rocker angles of 20°-30°. Finally, they report a reduction in pressure at the hallux with a 90° apex angle and increase with rocker angles 10° to 20°.

All rockers caused either an increase in pressure or had no effect on the heel, with pressure increasing significantly for all apex angles, for apex positions 50% through 60% and for rocker angles 20° to 30°. This finding correlates well with the findings of Brown et al (2004) and Hsi et al (2004) who also reported increases in heel pressures and decreases in the toe region.

Although the heel is not a common ulceration site for people with diabetes, it is important to be aware of the side effects of any intervention. What is more, an increase in pressure indicates a potential increase in vertical and/or posterior ground reaction force in early stance. The increase in force, unless the force passed directly through the joint would require greater moments to be produced by the lower limb musculature, which would increase the oxygen demand at these muscles and possibly reduce walking distances of individuals with PAD-IC.

Chapman's study provides thorough information on the effects of rocker sole designs on plantar pressures, and sets some general guidelines in the design of rocker soled shoes for individuals with diabetes. Specifically, to protect the forefoot from excessive pressures, Chapman et al (2013) recommend that rocker angle be kept above 20° and apex position below 60% of shoe length for single rocker soled shoes. Finally a 95° apex angle was found beneficial in distributing the load between the forefoot and hallux. The guidelines offered can be taken into consideration when designing shoes for individuals with PAD-IC, due to the high incidence of diabetes as a co-morbidity. However, this study only considered rocker soled shoes with one curve which means that the results may differ if further curves are incorporated into the sole design.

Gait kinematics and kinetics:

Studies that have investigated the kinematic and kinetic effects of rigid, therapeutic, rocker soled shoes on gait are limited. Myers et al (2006) studied kinematic and kinetic effects of the lower limbs when wearing a negative heel rocker soled shoe with a rigid metal shank (fig 2.11, by Myers et al, 2006).

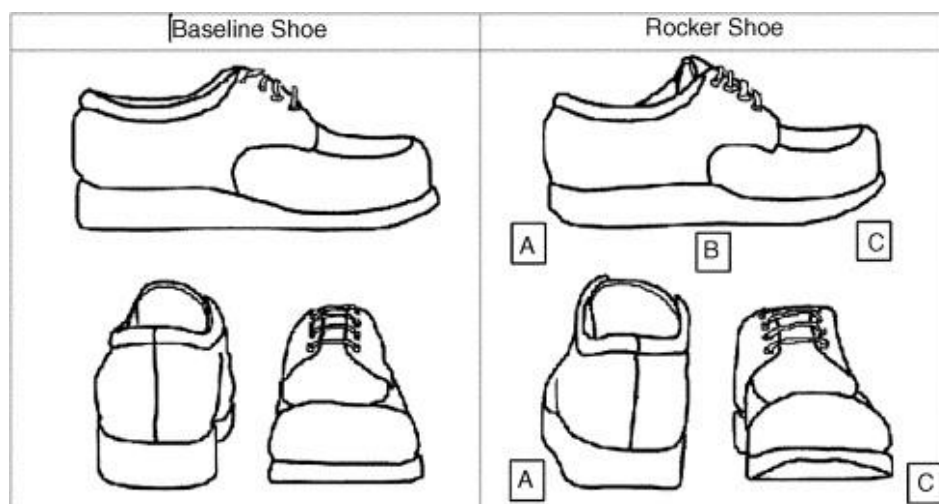


Figure 2.11: Baseline shoe and negative heel rocker sole shoe used by Myers et al, 2006.

Their findings show a significant increase in cadence but no changes of significance in walking speed and stride length. With regard to kinematics and kinetics, they report a decrease in hip flexion throughout the gait cycle, decreased dorsiflexion from mid-stance through swing, decreased internal ankle plantarflexion moment during late stance and foot off, increased ankle power generation during late stance and reduced ankle power generation at terminal stance. The reduced internal plantarflexion moment and power generation in late stance indicate a potential reduction of calf muscle activity which would be beneficial for individuals with PAD-IC. However, the information provided about the rocker sole used is that it was a negative heel rocker, the sole of which included a rigid metal shank. These design parameters are not sufficient to reproduce the shoe because there is no specification of the positioning of the apex of the rocker, or its angle to the ground or other geometric or functional features of the shoe. Furthermore, no explanation is provided about the reasoning behind the specific features of the shoe design and it is therefore difficult to associate specific design features with observed changes in gait data.



Figure 2.12: Double rocker sole shoe used by Long et al, 2007

Long et al studied the effects of a double rocker soled shoe (with a rigid metal shank to maintain sole shape) on gait of healthy individuals (Long et al., 2007). The apex of the front rocker was positioned behind the 5th metatarsal head. The anterior rocker is described as a toe rocker at 18°-20° to the ground. The posterior rocker is a heel rocker of 15° to the ground at 50% of the heel (fig 2.12, by Long et al. 2007).

The shoe was found to decrease internal ankle plantarflexion moment from mid-stance to mid-swing, compared to a control shoe with the same upper. Their finding

indicates a potential reduction in calf muscle activity at the time. Although no EMG data is available, and there is no explanation about the theory behind the shoe design, these findings, along with those of Myers et al (2006) prove that rocker soled shoes can successfully reduce ankle moment in late stance. However, the average decrease in plantarflexion moment in late stance, observed in the present study, was small (0.1 Nm/Kg) and would therefore not translate into a significant clinical effect. Furthermore, the shoe increased internal knee and hip flexion and extension moments throughout stance, suggesting possible increases in the forces required by the thigh muscles. In individuals with PAD-IC a force increase proximally at the thigh will require an increase in the oxygen supply. Therefore, the oxygen delivered to the calf will be reduced and the calf muscles may still claudicate over the same walking distance as when wearing an everyday shoe. In effect, changes imposed by the shoe at the knee and hip may cancel out any benefits at the ankle.

Peterson et al (1985) tested the effects of a single rocker soled shoe with apex position at 63% of shoe length and arc radius of 30.5 cm. The shoe had a heel height of 5.7 cm and a heel rocker that lifted the heel of the shoe 0.9 cm off the ground. The front rocker had a medial to lateral angle of 7° (fig 2.13, by Peterson et al, 1985).

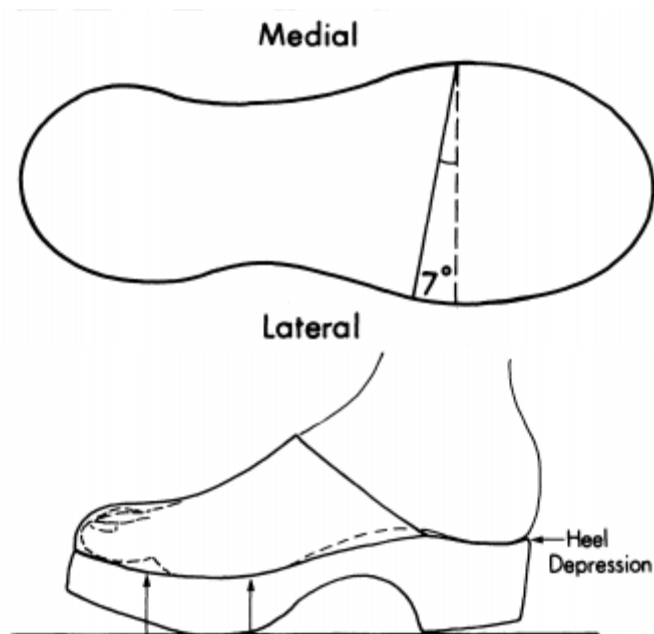


Figure 2.13: Rocker sole shoe used by Peterson et al, 1985.

The shoes were tested for kinematic, temporal-spatial parameters and electromyographic activity of the vastus lateralis, gastrocnemius and soleus on 15 young healthy women. The control shoes were laced, flat-sole running shoes made of canvas or leather and had a mean heel height of 0.7 cm.

The rocker soled shoes were not found to alter velocity, cadence, gait-cycle duration, single-limb support, swing-to-stance ratios or muscle activity. There was a reported increase in double limb support by 9% in the rocker soled shoes with self-selected walking speed. An increased loading rate was identified at heel contact and loading response, which would have increased the force demand on the extensor muscles to control ankle plantarflexion and knee flexion. A rapid off-loading of the foot was also reported. This does not appear to allow a smooth progression of the centre of pressure from the metatarsal heads to the toes, and is postulated to be the cause of the rapid loading of the contralateral limb also reported. This could be a contraindication for the use of this footwear for individuals with claudication. Furthermore, it highlights the importance of designing rockers that will enable a smooth transition from heel strike to toe-off.

Van Bogart et al (2005) studied the effects of a single, toe only rocker soled shoe on able bodied volunteers of average age of 43.4 years (2005). The shoes tested are described as toe only rockers, with a rocker apex at 40 -50% of shoe length and a rigid metal shank within the sole to increase stiffness (fig 2.14, by Van Bogart et al., 2005).

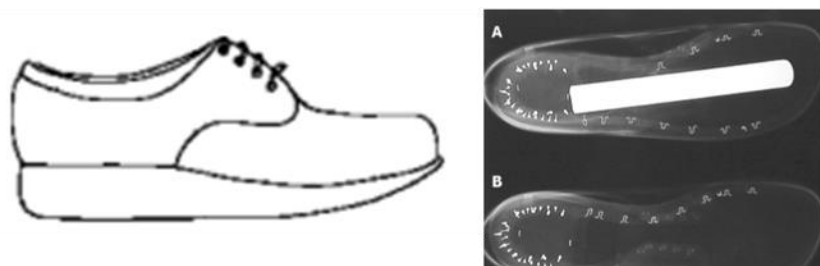


Figure 2.14: Toe only rocker sole shoe, used by Van Bogart et al, 2005.

Details about the radius of the arc of the rocker are not provided, only that it is tapered. Amongst their findings the study reports increased ankle dorsiflexion at initial stance and decreased internal ankle plantarflexion moment from mid-stance to terminal stance with the rocker soled shoe. These findings provide strength to the claim that a properly positioned forward rocker can indeed decrease moments at the ankle in late stance, which should, in theory, translate to reduced calf muscle activity. This however has not been tested in the above shoe design and the lack of shoe design parameters do not allow for the shoe to be replicated.

Walking distance:

Richardson (1991) tested the effect of a commercial shoe with a mild rocker of 15 degrees (set 6-7 cm proximal to the metatarsal heads) on walking distance of individuals with intermittent claudication (fig 2.15, by Richardson et al, 1991).



Figure 2.15: Rocker sole shoe used by Richardson, 1991.

The shoes were found to increase pain-free walking distances by 98 metres. However, the control shoe which was fitted with “placebo insoles” was not described. Furthermore, walking distance was rounded to the closest 5 metre increment which allows for an error of up to 10 metres. Also the lack of reported walking speed allows for the possibility that participants simply walked slower with the rocker soled shoe and were therefore able to walk longer without their calf muscles claudicating (reduced speed=reduced moment demand at ankle= reduced force demand from calf muscles=reduced oxygen demand). What is more, the findings were variable in that not all participants benefited from the shoes, as 7 out of 21 either gained no or only a marginal increase in walking distance (a third of the test population). It was postulated by the researchers that the variance was due to the differences between participants in the percentage of stance that they chose to apply push-off force through their calf muscles. This is, they argue, because the apex of the rocker was positioned posterior to the metatarsal heads, and therefore assisted heel off more so than toe off in terminal stance. In other words, they claim that individuals pushed off the ground sooner in stance and therefore the ground reaction force produced was closer to the ankle joint, causing a smaller moment at the ankle compared to if participants had pushed off with their metatarsal heads or toes. Indeed, the further the ground reaction force is from the ankle, the larger the dorsiflexion moment it creates and the larger the internal plantarflexion moment required from the calf muscles. But this does not fully explain the reduced effect of the rocker. Since the sole of the shoe appears relatively pliable and there is no mention of a metal shank within the sole, and the rocker angle from the ground is small and the thickness of the sole appears reduced after the apex (increase in thickness increased stiffness), it is possible that the sole deformed under load causing the rocker curve to be lost.

Running in rocker soled shoes:

Research is also available on rocker soled shoes when running and findings appear to be consistent with the effects in walking in terms of reduction in ankle moment and power. Sobhani et al (2017) investigated angles, moment and work at the ankle

knee and hip joints on 16 female endurance runners. Their findings indicated that, compared to the control shoes, rocker soled shoes reduced the peak internal ankle plantarflexion moment in stance as well as the peak positive and negative ankle work during stance. These changes were greater for mid-foot strikers than for rear foot strikers. Similarly, Boyer et al (2009) investigated the effects of running with and MBT shoe on 19 healthy individuals and report significantly reduced ankle moments and peak ankle power in stance compared to a controlled shoe.

Although the above findings support the use of rocker soled shoes to increase the walking distance of individuals with PAD-IC, the biomechanics of running are different to those of walking. Therefore, the effects of rocker soled shoes in running fall outside the scope of the current research as they do not apply to the patient group concerned. Previous research on the effect of walking with rocker soled shoes up and down stairs and slopes would have been pertinent to the current research as it could have possibly informed against certain shoe designs. However, no such research was identified.

Hutchins 3 curved rocker:

Hutchins et al (2009) offer the first descriptive review of the major types of rocker soles available and discuss how changing design parameters of the rockers, mainly the radius of curvature and position of the apex, cause significant changes to the lower limb biomechanics of gait. Hutchins (2007) subsequently designed rocker soles with PAD-IC patients as a target group and tested them in a small scale study, with 12 healthy young participants. The most effective designs were the 3 curve rocker (fig 2.14, Hutchins et al, 2012) and two curve rocker soled shoes

(fig 2.13, Hutchins et al, 2007).

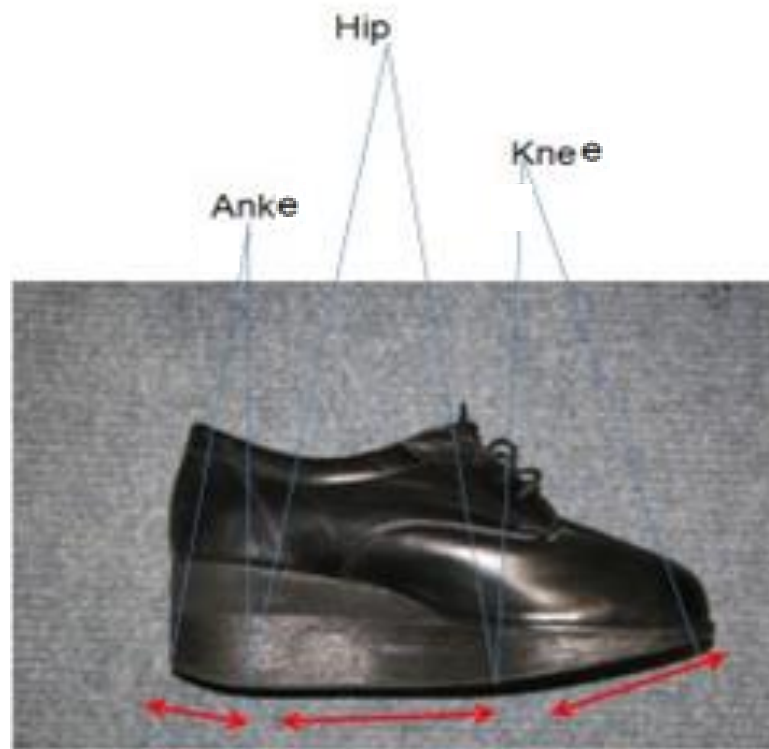


Figure 2.16: Three curve rocker sole shoe, depicting curve radii and centres, used by Hutchins et al 2012.

The three curve rocker sole was designed with three distinct curves at the sole (blended into one) and was very stiff to maintain the sole profile during stance. The radii of the three curves on the sole were designed such that the centre of the circles they describe coincide with the centres of the ankle, hip and knee joints respectively when an individual is standing (fig 2.16). More specifically:

- the first curve was based on a circle with a centre at the lateral malleolus and has a radius equal to the distance from the malleolus to the ground when an individual was standing
- the second curve was based on a circle with the centre at the hip and radius from the hip to the ground
- the third curve had its centre at the knee (lateral epicondyle) and a radius equal to the distance from the knee to the end of the shoe

The first curve began at the rear end of the shoe and was merged with the second curve at the level of the lateral malleolus. The second curve began at the end of the first curve and was merged with the third curve at 62.5 % of shoe length. The shoe was designed in this way so as to bring the ground reaction force closer to the lower limb joints throughout stance, thereby reducing the externally applied moments on the joints and by consequence the demand on the muscles. The 3 curve rocker was found to significantly increase pain free walking distance, by an average of 34.8 metres and to reduce pain severity by an average of 3.3 on a visual analogue pain scale (from 1 to 10) without causing unsteadiness or discomfort (Hutchins et al., 2012). It was also shown to decrease the average peak medial gastrocnemius (by $2.18\mu\text{V}$ compared to the control shoe) and peak tibialis anterior activity (by $6.76\mu\text{V}$ compared to the control shoe), although not statistically significantly. It must be noted that as these are differences of less than 10 millivolts in magnitude, it is equally likely that they may be attributed to noise and muscle recruitment variability. However, the reductions in ankle kinetics offer reason to consider that the differences may in fact reflect a valid reduction, albeit small. In any case, the effects of the shoe on the gait biomechanics of PAD-IC population have not been tested (Hutchins, 2007).

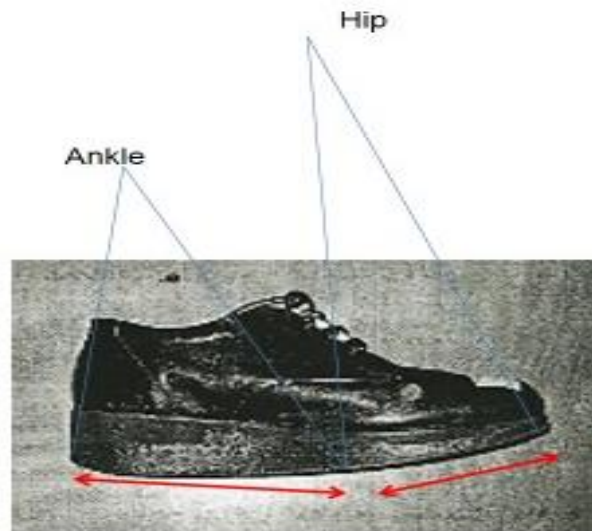


Figure 2.17: Two curve rocker sole shoe depicting curve radii and centres, used by Hutchins, 2007.

The two curve rocker soled shoe was designed using the same design principles as the three curve rocker. The posterior curve was centred at the ankle with a radius from the ankle to the ground. The anterior curve was centred at the hip with a radius from the hip to the ground. The two curves were merged together at the level of the lateral malleolus (fig 2.17). The shoe functioned similarly to the three curve rocker but due to the radii of the curves being larger, the foot would move more slowly through stance. The shoe was tested in a laboratory setting on 12 young healthy volunteers and it significantly reduced ankle dorsiflexion during mid-stance and range of ankle motion during heel rise and toe off (Hutchins, 2007). These findings were supported by a decrease in peak lateral gastrocnemius activity (by $1.12\mu\text{V}$ compared to the control shoe), and peak tibialis anterior activity (by $4.83\mu\text{V}$ compared to the control shoe) although these were not found to be statistically significant (Hutchins, 2007). However, no studies have been conducted to test the effects of the shoe on the gait of individuals with PAD-IC.

2.4 Effects of orthotics on gait

The literature supports the belief that individuals suffering from peripheral arterial disease likely demonstrate an increase in dorsiflexion during mid to late stance due to greater rotation of the tibia over the ankle joint (Chen et al, 2008) and in early stance due to muscle weakness (Celis et al, 2009). This increase in range of motion is likely due to the inability of the gastrocnemius, soleus and tibialis anterior muscles to adequately eccentrically contract to control this motion. A 'drop foot' or quick plantarflexion motion from initial contact to foot-flat has also been identified.

Any attempt to reduce the effects of PAD-IC on gait and to reduce the activity required by the calf muscles would involve applying particular forces at the ankle. These forces must reduce the ankle plantarflexion velocity during loading response, reduce tibial rotation over the foot during mid-stance and reduce the internal plantarflexion moment of the calf muscles during late stance. These objectives may, to an extent, be fulfilled with the use of orthotics.

Orthotics are designed to apply external forces and moments to joints in order to fulfil one of three purposes:

- To correct/prevent deformity
- To prevent worsening of deformities or provide support where deformities are present
- To improve function (Seymour, 2002)

For the purposes of managing intermittent claudication, orthotics can be used to serve the final purpose.

2.4.1 Orthotics for PAD-IC

Ankle-foot orthotics (AFOs) are orthotics that control ankle and foot motion and are worn inside footwear. There are several types of AFO designs available, made with materials of different compliance (fabric, plastic, carbon fibre) and have

designs that have different stiffness. According to these attributes, they offer different levels of support and restriction at the ankle and foot joints. Therefore, the most appropriate type, for assisting PAD-IC gait, first needs to be identified.

A reduction in excessive ankle dorsiflexion during mid-stance, in people with PAD-IC can be accomplished by applying a force normal to the tibia sufficient to resist its rotation. More specifically, treating the ankle and tibia as a beam rotating about a hinge joint (the ankle), if the joint was welded in place, rotation of the beam about its axis is lost. Therefore, if ankle motion is inhibited, tibial rotation in relation to the foot will be inhibited. The principle also applies during initial contact and loading response, where decreasing or minimising the motion of the ankle joint can effectively prevent rapid plantarflexion.

Reducing or minimising the range of motion (ROM) of the ankle joint should reduce contraction of the soleus and gastrocnemius muscle groups. This is based on the premise that eccentric and concentric contractions rely on the lengthening and shortening of muscles accordingly. If the ankle, the sole joint through which the gastrocnemius can extend and shorten to produce force and one of the two joints through which the soleus extends and shortens (the second being the knee) is immobilised, the activity at these muscles should decrease. It is true that these muscles are still able to isometrically contract or spasm. However, if progression of the stance limb is made possible by the use of appropriate rocker soled shoes, then there would be reduced demand on the calf muscles for force production. This should cause the neuromotor system to send a signal to the calf muscles which causes them to reduce or minimise their contractions throughout stance. Consequently, the oxygen required to fuel this lower level of activity should, in theory, be less. This should bring the supply and demand of oxygen at the calf closer to equilibrium, therefore prolonging pain free walking.

The above forces and joint motion restrictions may be applied with the use of a solid rigid AFO. Rigid AFOs restrict motion of the ankle joint in all planes. They are usually plastic and extend from the upper calf to the ankle joint and cover the medial and lateral malleoli. The foot plate extends to a position just behind the metatarsal heads where it is trimmed down to prevent the production of pressure

points. Alternatively, it extends past the toes. The first arrangement allows motion of the metatarsal phalangeal joints which assists in push-off, whereas the latter fully supports the joints of the foot, prohibiting motion. Rigid AFOs produce a posteriorly directed force at the tibial strap that applies a plantarflexion moment to the ankle, counteracting the external dorsiflexion moment of the GRF during mid-stance. For the AFO to fulfil this purpose a stiff material must be used. If the geometry of the AFO positions the ankle in slight plantarflexion it may also be used to control increased knee flexion during mid-stance. Rigid AFOs are commonly prescribed for individuals with plantarflexor and dorsiflexor weakness, both characteristics of individuals with PAD-IC, as well as persons with equinovarus caused by spasticity in the foot, weak knee extensors and proprioceptive sensory loss. Potential problems of this design are the increase in difficulty of foot rollover (tibial advancement over the foot) during mid-stance, and an inability to produce adequate power for push off (Richards, 2007, Seymour, 2002). The limitations of rigid AFOs can be overcome by pairing them with appropriate rocker soled shoes.

Combinations of lower limb orthotics and assistive rocker soled shoes have been used for decades in clinical practice for individuals with neurological problems such as cerebral palsy and spina bifida (Jagadamma et al., 2010). The combination is found to yield positive results, since the orthotic restricts unwanted motions while the shoes allow foot forward progression in gait. Specifically, the rocker soled shoes reduce external ankle moments by reducing the percentage of the ground reaction force which acts opposite to the progression of the foot through stance, while the AFO minimises the internal ankle moment, by generating moments that oppose the external moment from the ground reaction force.

To date, there has been very little research to parameterise the most effective AFO and footwear combinations for different lower limb deficiencies. Owen et al (2010) have laid the foundation in correctly pairing specific AFO and rocker soled shoe designs. However, their protocol was based on cerebral palsy (CP) and spina bifida patients.

Chapter 3: Determining and characterizing the knowledge gap

3.1 Gaps in the knowledge of PAD-IC gait

Studies to date do not provide a complete description of gait in PAD-IC since they are incomplete in the outcome measures used, the existing reports often contradict one-another and the differences in the study designs render them unsuitable for data to be pooled or a definitive synopsis created.

More specifically, only one study compared PAD-IC and healthy gait parameters at matched speeds (Wurdeman et al., 2012). The remaining studies do not control, or adjust for, the significant differences in walking speed. This is important because walking speed affects gait kinematics and kinetics and therefore many of the changes identified in the gait of individuals with PAD-IC may solely be the consequence of a reduced walking speed and not the disease itself.

Furthermore, authors do not fully agree on the changes present in moment and power at the knee and hip. Therefore, one cannot be certain of the relevance of the knee and hip moments when people with PAD-IC walk without pain and, as a result, of the impact of the disease on proximal muscle function during gait. This has an impact because it is these external moments and joint powers that interventions might target in order to reduce force and oxygen demand in lower limb muscles.

Another notable discrepancy amongst studies is their findings in ankle kinematics. More specifically, both Chen et al (2008) et al and Celis et al (2009) report increased ankle plantarflexion in early stance while Gommans et al (2016) report a reduction in early stance peak plantarflexion. Only Chen et al (2008) describe a significant increase in peak ankle dorsiflexion in mid-stance and only Crowther et al (2007) support a significant decrease in peak hip extension in mid to late stance. It is important to determine whether and to what extent these changes are present, because they provide insight as to the muscles that are most likely affected by the disease, as well as the degree to which they are affected. In this way, any shoe or orthotic intervention for this patient group can be chosen, designed or altered accurately to deliver a specific effect to these muscles.

There are also issues with the patient groups involved. Koutakis et al (2010a) used patients with aortoiliac and combined aortoiliac and femoropoplital disease, as opposed to Chen (2008) who only used participants with femoropoplital disease. This can explain the significant results identified more proximally (at the hip). However, Koutakis et al (2010a) is the only study to specifically test individuals with aortoiliac claudication. Consequently, it cannot be certain that their results are a reflection of more proximal blockage and even if they are, they have not been officially identified as such. Similarly, differences in outcome measures between studies may be the result of some studies reporting on individuals with unilateral PAD-IC, others on individuals with bi-lateral PAD-IC and others on a mixture of both. Although determining the gait characteristics of each of the above subgroups, compared to healthy controls, is beyond the scope of the present research (as it constitute a separate research question) it is important that previous findings are verified for a general PAD-IC population. By doing so, decisions can be made as to which internal moments and powers the shoes, and any orthotic used, must focus on reducing to provide benefit to the majority of individuals affected by the disease, irrespective of subgroup.

Finally, previous studies do not attempt to assess the differences in peak muscle activity during gait in individuals with PAD-IC in comparison to healthy counterparts. This would be a strong indicator of the effect that the disease related changes in muscles have on individuals' choice of and/or capacity for peak contractions during gait. It would also set some quantitative targets for gait interventions in terms of changes in moments or powers. It is therefore imperative that an accurate and comprehensive model of PAD-IC gait is built. This will serve as a valuable platform from which an appropriate intervention can be developed.

3.2 Shortcomings and problems of previous footwear designs

Whilst there is plenty of literature on rocker soled shoes, the majority of studies consider plantar pressures in rocker shoes, primarily for diabetic patients and independent of PAD-IC, (Chapman et al., 2013, Albright and Woodhull-Smith, 2009, Stewart et al., 2007, Brown et al., 2004, Kavros et al., 2011) whereas it is known that it is gait and muscle function that are affected by PAD-IC.

The majority of studies on the effects of rocker soled shoes on muscle activity have tested healthy individuals in exercise shoes and mostly MBT footwear in comparison to standard shoes/running shoes (Horsak and Baca, 2013, Sousa et al., 2012, Sacco et al., 2012, Stewart et al., 2007). Although different studies report different degrees of shoe effectiveness, collectively the literature agrees that MBTs can cause a slight increase in calf muscle activity in the short term. The effects of these shoes on muscle activity, although not strong, render them unsuitable as a means to increase PAD-IC pain-free walking distance. Conversely, they suggest calf activity can be manipulated by changes in footwear design and perhaps different designs could have advantages for people with PAD-IC.

Kinematic and kinetic studies on rocker soled shoes, where the rocker is not an exercise shoe, are few. Myers et al (2006) reported effects of the negative heel rocker that may be beneficial to reducing internal moments and hence potentially muscle activity in PAD-IC patients. However, the information provided on the design of the shoe is not adequate to reproduce it. Peterson et al (1985) reported a significant increase in loading rate after initial contact, which would indicate an increase in the demand for force production but the lower limb muscles, and a rapid unloading of the contralateral limb, both of which are unwanted for individuals with PAD-IC. Long et al (2007) adequately describes the double rocker design in his study, but the shoes investigated significantly increased moments at the knee and hip and did not substantially decrease internal ankle plantarflexion moment in late stance. Van Bogart et al (2005) conducted a study investigating a single forward rocker soled shoe design. This design caused alterations in gait that would benefit individuals with PAD-IC, such as reduction in internal plantarflexion moment in late

stance. However, not enough data is provided on the shoe design. Furthermore, these designs have since been improved upon by Hutchins (2007). Hutchins offers both adequate design guidelines for the three and two curve rocker soled shoes which he investigated, and their effects on the lower limb kinetics and muscle activity could have a significant positive impact on pain-free walking distances of individuals with PAD-IC. These therefore offer some promise.

3.3 The Problem with Hutchins's design

The literature highlights Hutchins's designs as having the most potential as a suitable biomechanical intervention gait of people with PAD-IC and thus this could form the basis of the work in this thesis. Whilst the designs were based on biomechanical theory which results supported, the kinematic, kinetic and EMG effects have only been evaluated in a small-scale study (12 participants for kinematic & kinetic data and 8 for EMG), using young healthy participants. Since there are known changes in gait of individuals with PAD-IC and muscle function further testing is required.

More importantly, upon studying the thesis that developed the three and two curve rocker soles (Hutchins, 2007), and after corresponding with the author, a discrepancy between the theory and design was identified (which he was made aware of). Specifically, while the theory dictates that the curves of the rockers are meant to be centred at the lower limb joints, the distances from the joints to the ground were taken in a barefoot condition. Therefore, the thickness of the shoe sole was not accounted for in designing the arcs for the soles and thus in the prior work the curves would not have been centred at the joints as assumed. This is important because it signifies that any effects of the shoe, documented in healthy individuals, may well not be the result of the shoe features in the way which was theorised. Alternatively, it signifies that the tolerance of the shoe curves to deliver a positive effect is potentially wide.

Hutchins offers a rudimentary biomechanical explanation of the three curve rocker soled shoe. He states that, by centring the circles on which the shoe sole curve is based, at the ankle, hip and knee accordingly, the curve helps keep the GRF closer to the anatomical lower limb joints during stance, which reduces the external moments at these joints and by consequence the internal moments and thereby demand for force production by the muscles. However, this explanation is still basic in its analysis and does not take into account the effect of the angular velocity and acceleration of the shoe and the effect of body weight. The following section offers a more detailed biomechanical analysis of the function of three curve rocker soled shoe during gait. This helps to determine features of a rocker soled shoe that would render it beneficial for individuals with PAD-IC and acts to support the choices of rocker soled shoes used in the present research.

3.4 Biomechanical explanation of the three curve rocker soled shoe

When considering the gait cycle especially with regard to the ankle, there is a tendency to focus on the shank-foot system. The mass of the foot is taken into account but the centre of mass (CoM) at the pelvis is not usually discussed. By consequence when moments are considered about the ankle, the moment created by the weight (F_{com}) (fig 3.1) at the centre of mass of the body of the body is not directly considered, only assimilated into the force acting on the ground. However, in the current research it is important to take this mass into account as it is responsible for a large moment. This moment tends to rotate the curved sole of the shoe forward and therefore assists the action of the calf muscles, in lifting the heel.

More specifically, as soon as the centre of mass of an object moves outside the base of support, the system becomes unstable. In the case of gait in a three curved rocker soled shoe, because the sole is curved, only part of it makes contact with the ground. Therefore, as soon as the centre of mass of the body at the pelvis moves outside the base of support, the system becomes unstable and rotates forwards. The front end of the base of support of the three curve rocker soled shoe is closer

to the ankle joint than that of an everyday shoe. Therefore, the system will become unstable and rotate forward before it would if one were to lean forward while balancing on one bare foot.

When barefoot, if we consider the foot as a structure with two hinge joints, one at the ankle, and one at the metatarsal heads, the system becomes unbalanced when the large centre of mass at the pelvis is in front of the centre of pressure (CoP) much like an inverted pendulum (Winter et al, 1995). Until then, it is the force created by the calf that would control lifting of the heel. On the contrary, with the rocker soled shoe, the system becomes unbalanced before the GRF reaches the metatarsal heads, which means that from the moment the system becomes unbalanced in the forward direction, the input of the calf force can be reduced or minimised because the moment applied by the centre of mass of the body at the pelvis to the shoe takes on that role.

Furthermore, because this is a rocker sole with three curves moulded into one, the system never goes through a time of equilibrium where it balances. As the shoe-foot makes contact with the ground (initial stance), the system tends to want to reach equilibrium, which is the centre of balance/base of support of the system.

This tends to move the CoP forward (rotate the foot forward). Furthermore, when the heel makes contact with the ground the foot-shoe CoM also has a linear (forward) velocity (fig 3.1). Any curved object that has a linear velocity and is in contact with the ground will also have an angular acceleration due to frictional force (F_{friction}) acting on the object (assuming little to no slipping between surfaces) (fig 3.1). Therefore, this angular acceleration, in conjunction with the system's desire to reach equilibrium, will rotate the system to the centre of balance of the shoe-foot. This equilibrium position is reached but because the sole maintains an angular velocity, and the CoM of the body has now moved in front of the base of support of the foot-shoe, the latter will continue to rotate forward and by consequence lift the heel (fig 3.1).

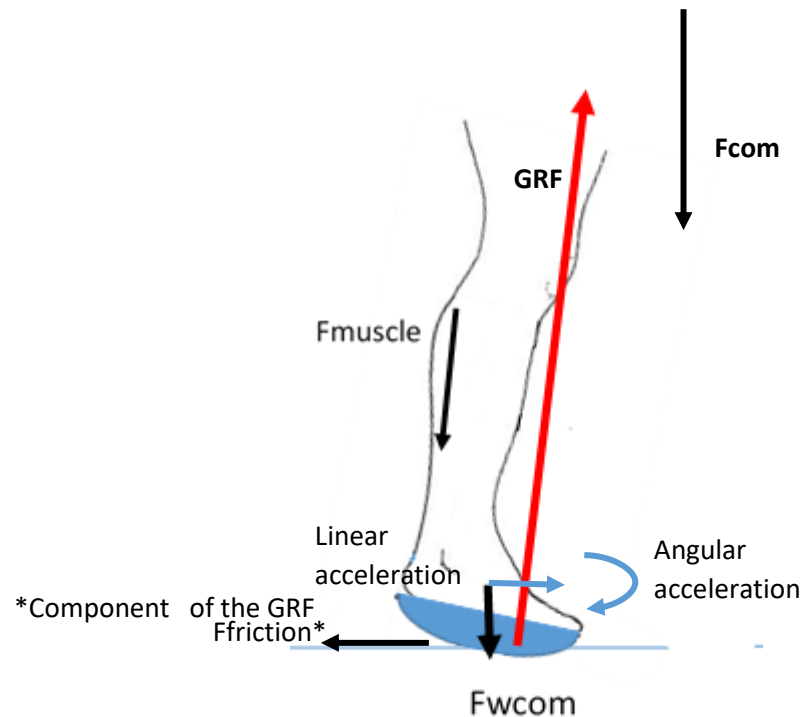


Figure 3.1: Forces acting on the foot and rocker sole shoe during late stance phase of gait.

3.5 Justification for the use of the specific three curve rocker sole design

The above analysis alone does not highlight a need for the shoe to consist of three rockers, only for the entire sole of the shoe to be curved. Furthermore, it does not highlight a need to have the curves centred at the ankle, hip and knee accordingly. However, the following paragraphs will explain why the design features chosen by Hutchins are preferable.

In a one curve rocker soled shoe, the closer the apex is to the ankle joint the sooner the system reaches imbalance (during stance phase progression). The GRF would be closer to the ankle joint as the heel is lifting, creating a relatively smaller external moment at the ankle and the moment applied by the body's weight (mass*gravity) as it moves in front of the CoP to the foot-shoe, would become progressively larger. This would greatly reduce the requirement for muscle force production and thereby

oxygen demand. However, in order for the shoe-foot system to balance when an individual is standing, the apex of the curve must be situated at no further back than midfoot; that is in front of the ankle joint and closer to the metatarsal heads. If this were not the case the individual would need to actively work (muscle activity) to maintain balance.

If the curve of a one curve rocker soled shoe, where the curve covers the full length of the shoe, were based on a circle with a large radius, the base of support would be large (which assists balance) but the angular velocity of the shoe at any given time point and its angular acceleration would be smaller because the radius is inversely proportional to angular acceleration ($\text{angular acceleration} = \text{linear acceleration} / \text{radius}$). Therefore the shoe would be less effective at assisting the work of the calf muscles than one with a smaller radius.

Conversely, in a one curve rocker soled shoe, where the curve covers the full length of the shoe, the smaller the radius of the curve the smaller the base of support (if one assumes the same position of apex) and the larger the angular acceleration of the shoe during gait. If the rocker radius were too small, the sole of the shoe would have to be very thick, which in conjunction with the small base of support would make too unstable a system. Previous research has highlighted one curve rocker soles with a radius of 0.3 and 0.4 % of leg length as the most effective at reducing oxygen consumption (highest energy efficiency). These shoes however, were tested on healthy individuals whose lower limb musculature has not been compromised. It is therefore likely that individuals with PAD-IC would struggle to maintain balance in relation to their healthy counterparts. Equally importantly, the greater muscle activity required to maintain balance when standing and to control CoP progression during gait is opposite to the aim of footwear for individuals with PAD-IC.

An answer to this issue is somewhat given by the two curve rocker shoe design by Long et al (Long et al., 2007). This design offers two curves, a heel and a forefoot curve with a domed surface under the midfoot to stabilise the system during mid-stance. While such a shoe is more stable than a one curve rocker, because it encourages a point of static equilibrium to be achieved more easily during mid-stance and standing, it also nullifies the angular velocity created by the first curve

at the sole of the shoe. Therefore, the angular velocity as the second rocker is reached (around the metatarsal heads) is zero. On the contrary in the three curve rocker soled shoe, the angular velocity of the sole is present constantly and assists in the reduction of ankle moment in late stance. Consequently, a three curve rocker sole design should cause superior effects (greater reduction of ankle moment, power) than a one or two curve rocker.

There is no specific biomechanical explanation identified for placing the centres of the three circles at the ankle, hip and knee accordingly, although this does not necessarily mean that a biomechanical connection does not exist. What can be said is that using a small radius of curve from heel contact to the beginning of mid-stance, ensures that sufficient angular acceleration is generated. In mid-stance the foot is usually stationary and this provides balance. A small curve during this period could cause the centre of pressure of the foot to progress too quickly, create imbalance to the individual and cause falls. Therefore, a large radius such as the one with a centre at the hip ensures that a degree of angular acceleration is maintained. Finally, just before the metatarsal heads, a smaller rocker radius than the previous should be present to increase angular velocity and assist in bringing the foot to toe-off. Although the current research will not focus on analysing a range of rocker sole curves, the rockers which will be studied will allow for a level of understanding of the effect of altering these radii.

3.6 Aims and Objectives of the PhD:

The aim of this research is the development of footwear to help in the management of PAD-IC. Informed by the literature review, the objectives are:

1. To characterise gait in people with PAD-IC
2. To determine the effects of rocker sole profiles and AFO on lower limb kinematics, kinetics and muscle activity in people with PAD-IC

3. To determine the effectiveness of the most effective footwear intervention in a simulated real world environment
4. To suggest improved footwear and AFO designs based on the results of (2) and (3).

In order to meet these objectives three pieces of experimental research were undertaken and these are described in chapter 5-7. In the next chapter (chapter 4), a reliability study is conducted to ensure that all subsequent research and findings are reproducible. In chapter 5, the gait in individuals with PAD-IC is compared to age matched healthy individuals. In chapter 6 the effects of different rocker soled shoes, used alone and in combination with an AFO on gait kinematics, kinetics and muscle activity of individuals with PAD-IC, are investigated. The effectiveness of the most effective footwear condition is then investigated in real-world environments in chapter 7. Finally, in chapter 8, the contributions of the thesis are outlined and recommendations for the improvement of the intervention made.

Chapter 4: Methods

All studies in the present thesis received approval by the university ethics committee (Number HSCR13/91) prior to any data collection taking place. Since amongst study subjects were NHS patients with PAD-IC, the studies which will be presented in the following chapters received NHS ethics approval by the NHS Brighton and Sussex NRES Committee (study number: 14/LO/0382) and the North West - Greater Manchester South Research Ethics Committees accordingly (Number 16/NW/0139). The present chapter will outline the methodologies used in the studies conducted for this research, through applying them to the repeatability analysis which was conducted prior to the studies, on healthy individuals recruited from the University. Further details on each individual study design (inclusion/exclusion criteria and ethics approval) are reported in the respective chapters.

In order to measure the biomechanics of gait in individuals with PAD-IC and the effects of footwear on this gait, lower limb motion, force and muscle activity data need to be captured during locomotion. The next sections will detail the procedures undertaken, to collect this information, within the studies reported in chapters 5-8.

4.1 Equipment, Guidelines and Calibration

Kinematic data

Kinematic data was captured at 100Hz using the Qualysis computerised motion analysis system (Qualysis, AB, Gothenburg, Sweden), Qualysis Track Manager (QTM), version 2.11 software and 15 Oqus cameras. Red-spectrum light is reflected by reflective markers, which are placed on the limbs and trunk of volunteers, back to the cameras and provides the 2-D position (X, Y) of each marker in space. Each marker must be captured by at least two cameras (two rays or red light seen) at any one time during data collection time in order for its 3-D location to be determined

within the global coordinate system (Cappozzo et al., 2005, Payton et al., 2008, Kaufman and Sutherland, 2006). This requires a minimum of three non-co-linear reflective markers per segment to accurately identify its position and orientation in a 3-D space (Cappozzo et al., 1996).

System calibration

At the beginning of each data collection session the lab was calibrated by placing an L-shaped frame mounted with four reflective markers at distances of: 570, 200 and 370 mm, at the grooves of the 1st force plate and in line with the gait pathway (fig 4.1). A wand was waved through the calibration space for the purposes of dynamic calibration and was mounted with two reflective markers set at a distance of 601.7 mm (fig 4.1). The duration of the calibration was set to 1 minute for a calibration volume of 8m by 3.5m by 2m.



Figure 4.1: Image of calibration wand (right) and calibration frame (left).

The Qualysis Track Manager software (QTM) software processes the calibration and offers a set of resulting values. Amongst these is the average of residuals which expresses the difference between the static marker coordinates and the actual coordinates in 3-D. The average residual must be as low as possible so that the

virtual coordinates are an accurate representation of the actual markers. A calibration is considered successful if the average of residuals is less than 1 mm (CMAS University of Salford lab standards) and of higher quality the smaller the values are. In the current study only calibrations with resulting average residuals ≤ 1 mm were used.

Kinetic data

Kinetic data was collected by capturing the ground reaction force. This was measured at 1000Hz, using force plates (BP400x600, AMTI Watertown, MA, USA), which were imbedded into the floor of the laboratory using strain gauge technology. Two force plates were used for the collection of ground reaction force (GRF) data for the right and left limb. Data collection for GRF was synchronised with kinematic data collection and collected by Qualysis Track Manager (QTM) (Qualysis, AB, Gothenburg, Sweden) software. Both force plates were positioned and calibrated, using CalTester software, by the centre engineers, in accordance with internal laboratory procedures by technical staff. This software is a quality assurance tool used for validating the laboratory settings of force plates. It functions to corroborate the spatial synchronisation of the force plates and forces (C-Motion, 2016). The CalTester test results identified the accuracy of the force vector orientation as $\leq 1^\circ$ and COP location as ≤ 3 mm, for both force plates (CMAS University of Salford lab standards).

Coordinate system

A Cartesian coordinate system that describes the positions of the markers in 3-D space was adopted. The system has three axes: x, y and z and was used based on the recommendation of the International Society of Biomechanics (ISB)(Wu and Cavanagh, 1995). The x-axis of the system points in the anterior-posterior direction, in parallel with the line of progression. Values are considered as positive along the line of progression. The z-axis is the vertical axis, in parallel with the field of gravity, with positive values in the upward direction. The y-axis is medial to lateral with respect to the line of progression, and perpendicular to the x and z axes. Values on the right are considered as positive. The Cartesian coordinate system follows the

right hand rule, which states that when the thumb of the right hand points along an axis, in the positive direction, the fingers curl around the imaginary vector line of the axis and the tips point in the direction of the positive rotation of that axis.

Marker placement model

In order to collect 3-D kinematic data, retro-reflective markers are placed on the individual. Any single cartesian coordinate system requires a minimum of three markers in order to be defined. This translates into three markers being placed on each body segment. An additional two markers are required to define an axis of rotation; which translates into two markers being placed on the joint line. Therefore, in order to fully calculate the displacement of two adjacent segments in a 3D space, a minimum of eight markers are required.

In theory, the relative displacement of two adjacent segments could be defined by using only four markers in total, two to define/calculate the common joint centre and one on each segment to define the relative motion between the two. However Cappozzo et al (Cappozzo et al., 1996) have shown that in such a configuration, skin movement artefacts, meaning the displacement of a marker from a bony landmark due to movement of the skin, can be as great as 20mm.

In answer to this problem, Cappozzo et al (1995) introduced the calibrated anatomical systems technique (CAST) method. This is a static calibration technique with which the position of each joint centre in dynamic trials is determined solely by the use of segment defining markers. This method is based on the logic that the orientation and position of joint defining markers should remain the same, except for movement artefact. The position and orientation of the joint markers are mathematically determined in the static calibration. These markers can then be removed and the original positions computed using only the segment defining markers in dynamic trials. Cappozzo's method offers six degrees of freedom to the joint, allowing for the computation of the relative motions and rotations between two segments (Kirtley, 2006). With regard to the number of markers on a given cluster, used to determine a segment, both Cappozzo et al (1997) and Manal et al (2000) recommend the use of four markers on a segment mounted cluster. The use

of a cluster minimises independent movement artefact of the markers in the global coordinate system, while the use of four markers (three as a minimum requirement and one as supplementary) allows for reliable tracking of a segment even with the loss of one marker. The current study followed the CAST marker set-up.

EMG electrode placement

EMG data was collected using the Noraxon TeleMyo (TeleMyo 2400T G2, Noraxon U.S.A. Inc) system. This was synchronised with the kinematic and kinetic data and stored in QTM.

Capturing high quality electrical signal depends on a number of parameters. To begin with EMG records and transmits electrical activity as the number of motor units that fire around a specific site. Therefore, if the electrode is placed at the edge of the muscle where less neurons will fire, the signal that will be recorded will be a weak signal. In addition, the signal will not be a true reflection of this muscle's activity because the electrode is not in the region of highest motor unit firing and will hence give a false reading of that muscle's activity. Furthermore, if the electrodes are placed closer to the edges of the muscle there is a high risk of recording cross-talk from other muscles close to that location, which will contaminate the true signal. SENIAM (Hermens H.J., 2008) guidelines offer direction on the most appropriate sites to place electrodes for the recording of a signal for most major muscles (Hermens H.J., 2008). Specifically, they identify the optimal position for electrode placement for many muscles according to the highest concentration of neuron firing. This location is usually determined as the middle of the muscle belly, between the nearest innervation zone and the myotendinous junction (site of connection between tendon and muscle) (De Luca., 1997). Their guidelines were therefore used to maintain accuracy and high quality results in the present research.

A second issue when using surface EMG, is that the signal that is being recorded, is done so through a layer of fat and skin (De Luca, 1995, HERMENS H.J., 2008). The greater the layer of fat between the muscle and the skin, the poorer the quality of the signal. This is an issue that cannot be removed but rather needs to be reported and understood for the particular muscles and patient groups being investigated.

Using intramuscular EMG, which involves insertion of an electrode into the muscle itself, would be a way to by-pass this issue. However, the radius of the pins on the electrode only transmit the neuron activity in their immediate vicinity and may therefore fail to give a full picture of the overall activity of the muscle (HERMENS H.J., 2008). These invasive methods are also not always applicable, especially when dealing with a clinical group with impaired health, such as those with PAD-IC.

A third issue when capturing muscle activity with surface EMG is the conductivity of the skin (De Luca, 1997). In order for the signal to be picked up by the electrodes, the skin must be conductive to electricity. Dead skin cells and microscopic dirt lower the conductivity of the skin and produce a poor signal. To confront this issue, before the application of the gel electrode, the skin is abraded using abrasive paste, which removes hard and/or dead skin cells and oils and dirt. The skin is then cleaned using alcohol wipes and allowed to dry before electrodes is placed. In the current research, after the electrode sites were identified and marked with a pen, skin hair was removed using a razor. Abrasive paste and alcohol wipes were then used for skin preparation.

When collecting EMG using a hardwired system the motion of the wires must be taken into account. Movement of the wires is common and will introduce noise into the system. It is very important that this noise is minimised in order to have a good quality signal. This is achieved by securing the wires with tape and bandages around the limbs. If small amounts of noise remain, these will later be filtered out with minimal impact on the quality of the processed signal.

Finally, when recording surface EMG, more than one gel electrode is needed to record a reliable amount of muscle activity, which is why it is recommended that two electrodes are used per muscle (De Luca, 1997). In order for these to give a reliable result they must be placed no further apart than 20 mm. Double electrodes, such as the one in figure 4.2 below, that offer two electrodes fused in one and are readily available and were used in the current study.

When collecting with the hardwired Noraxon system, a separate ground or reference electrode (figure 4.2), (2 cm x 2 cm) must be placed on a bony

prominence. This serves as a reference for the noise which is then filtered out of the signal. It is essential that the ground electrode make good electrical contact with the skin. In the current study, the electrodes were placed on each muscle in the direction of the muscle fibres according to SENIAM guidelines.



Figure 4.2: Double electrodes and single electrode used as ground electrode.

Despite precautions against EMG signal disruption from extrinsic factors, there are still intrinsic factors associated with EMG data collection which limit the accuracy of the signal and our ability to quantitatively connect it to muscle activity and work done (De Luca, 1995). Specifically, the peak amplitude of the signal is dependent on the number of motor units recruited during the contraction and the number of motor units recruited for a specific activity may not be the same during each repetition of the activity. It may also vary between individuals, all leading to different EMG amplitudes. This can be misleading and explain the relative disparity between the ability of a muscle to produce force and EMG signal. Furthermore, muscle fibre composition differs in different muscles and individuals and can affect EMG amplitude, with greater type II fibres producing greater amplitudes. Muscle fibre diameter can also vary considerably between individuals and the greater the diameter, the greater the amplitude and conduction velocity of the electrical signals (De Luca, 1995). Consequently, what appears as a larger (in amplitude) contraction may simply be the result of greater diameter of muscle fibres. Finally, blood flow to the muscle affects the speed with which nutrients are transported during a contraction and by consequence the power of a contraction (De Luca, 1995). These

are inherent limitations in the analysis of EMG and it is for this reason that the interpretation of EMG findings should be conducted with caution and alongside kinetic findings rather than as a main outcome measure.

In order to be able to compare EMG signals between individuals and groups the EMG signal must first be normalised (De Luca, 1997, Perry, 1992, Cram, 1998). There are several methods of normalisation available, each offering their own benefits. It is generally accepted that normalising EMG signal to the maximal voluntary contraction of an individual offers reliable signals and allows for comparison of muscle innervation levels (Burden & Baltzopoulos, 2003). This method of normalisation is also indicated for studies comparing healthy and clinical populations, such as individuals with knee osteoarthritis and healthy controls (Rutherford et al, 2011). However, if certain clinical populations cannot easily perform a maximum voluntary contraction due to disease or pain, other accepted methods of normalising would be to the peak or mean activation levels during the examined task. Normalising to the peak or mean of an activity has been shown to significantly reduce inter-individual variability compared to normalising to the maximum voluntary contraction (Burden & Baltzopoulos, 2003). However, they have the innate limitation that the data on the true signal is lost. Therefore, direct comparison of innervation levels between groups is not possible. The methods however still lend themselves to comparing the behaviour of the muscle and, in combination with findings on kinetics and raw EMG data, can allow for confident inferences to be made regarding innervation levels between groups.

4.2. Repeatability Analysis

4.2.1 Introduction

In order for the results of a research study to be acceptable, one must first prove that they are repeatable. Kinematic and kinetic data collection can be a repeatable and accurate process but there are a number of factors that can introduce errors into the measurement. These include faulty equipment, incorrect or inconsistent

marker placement, inconsistent participant walking speed between test conditions, a poor calibration of cameras or a poor calibration of force plates (incorrect CoP on force plates) and finally, errors in data processing. Therefore, a repeatability analysis is necessary prior to data collection to determine the level or reproducibility in results and the random error in measurement.

Marker placement has been shown to introduce a significant degree of variability to kinematic measurement (Cappozzo et al., 1996) as it relies on placing markers by palpating and correctly identifying bony prominences. This task is often difficult as these prominences are covered by layers of muscle and fat. It is therefore essential to determine that, throughout a study, marker placement is consistent and introduces only minimal errors to the measurement. Having the markers placed by one individual, as is the case in the current research, reduces the amount of variation present as they are more likely to be consistent in their method of placement, whereas placement methods between two individuals may vary (Maynard et al, 2003).

However, this measure is not enough to ensure acceptable repeatability. This must be proven by examining the repeatability of biomechanical outcome measures in a set of individuals in two separate measurement sessions. Within this time, it is highly unlikely that basic outcome measures of these individuals' motion would change significantly. Therefore, any change identified can be attributed to errors in repeatability or processing. However, since the same software and processing code/pipeline would be used for the analysis of both sets of data, it is safe to assume that significant changes in relevant parameters will have most likely been introduced from variability in marker placement between the two data collection sessions and the normal variation in gait. Data on normal gait variability of healthy and patient groups is often available in the literature and can provide guidance as to whether variability observed in a repeatability study can be attributed to normal variability in the group or should likely be attributed to marker placement error.

The test - re-test repeatability can be measured by calculating the intra-class correlation coefficient (ICC). The intra-class correlation coefficients can be interpreted, as suggested by Coppieters (Coppieters et al., 2002) as follows:

excellent = > 0.90, good = 0.70-0.90, fair = 0.40-0.70, poor = <0.4. The test - re-test reliability can be found by calculating the standard error of measurement (SEM) which will allow for the calculation of the minimally detectable significant difference (MDD) in outcome measures. This represents the minimal change in an outcome measure that can be safely attributed to a valid change in a participants' biomechanical motion and not to normal variation in gait or marker placement error. All resulting values within the study that are above the MDD can be considered as both statistically and clinically significant (Kropmans et al., 1999). The minimally detectable difference is more variable in its interpretation as this will depend of the specific outcome measure studied. For example if a specific intervention is meant to increase maximum plantarflexion by five degrees and the MDD is five, this means that the observer cannot be certain about any smaller increases of plantarflexion identified. This would qualify as a very bad result. Generally the aim is to keep the MDD as low as possible so that any changes identified by an intervention can be safely identified and attributed to that intervention.

4.2.2 Aim

To calculate the test-re-test repeatability of data collection of normal gait.

4.2.3 Methods

The current methods section outlines the methodology used for the analysis of repeatability, as well as for the studies, in chapters six to eight. Methodology aspects of each study are summarised within each chapter and reference is made to the current chapter for further detail.

4.2.3.a Participants

Five healthy participants of ages 25 – 50, in self-reported good general health with no injury to their legs or spine, surgery in the past 3 months of gait altering

conditions, were recruited from within the staff and post graduate student population at the University of Salford via email (through the school secretary). This contained the information sheet and an invitation letter. Individuals who were interested could respond to the email to ask further questions and, if willing, to set a date for participation in the study. Individuals who were not interested in taking part could simply ignore the email. The study was approved by the university ethics committee (Number HSCR13/91). Testing was conducted in the clinical gait laboratory at The University of Salford.

4.2.3.b Data collection

Prior to participants entering the lab, safety was ensured by checking that any equipment in close contact with participants, such as the timing gaits, were balanced and stable. Upon arrival participants were made aware of the testing procedures and offered the consent form pending their initials and signature. Provided the participant was still willing to undergo the testing, they were directed to the changing rooms so as to change into their shorts and T-shirt. Upon return, the participant was asked to lie on a medical bed while the sites for EMG electrode placement were identified, circled with a pen and shaved if necessary. These were then rubbed with abrasive gel, followed by alcohol wipe as directed by SENIAM guidelines (table 4.1, fig 4.3). Participants were asked to stand up and wear a neoprene vest onto which the EMG transmitter was secured. EMG electrodes, with an inter-electrode distance of 2cm, were placed on the tibialis anterior, medial and lateral gastrocnemius and soleus muscles of both legs, and attached via wires to the transmitter.

Table 4.1: SENIAM guidelines for the placement of electrodes on the tibialis anterior, medial gastrocnemius, lateral gastrocnemius and soleus muscles.

Muscle	SENIAM guidelines for electrode placement
Tibialis anterior muscle	1/3 on the line between the tip of the fibula and the tip of the medial malleolus
Medial gastrocnemius	Centre of the most prominent bulge of the muscle
Lateral gastrocnemius	1/3 of the line between the head of the fibula and the heel
Soleus	2/3 of the line between the medial condylis of the femur to the medial malleolus

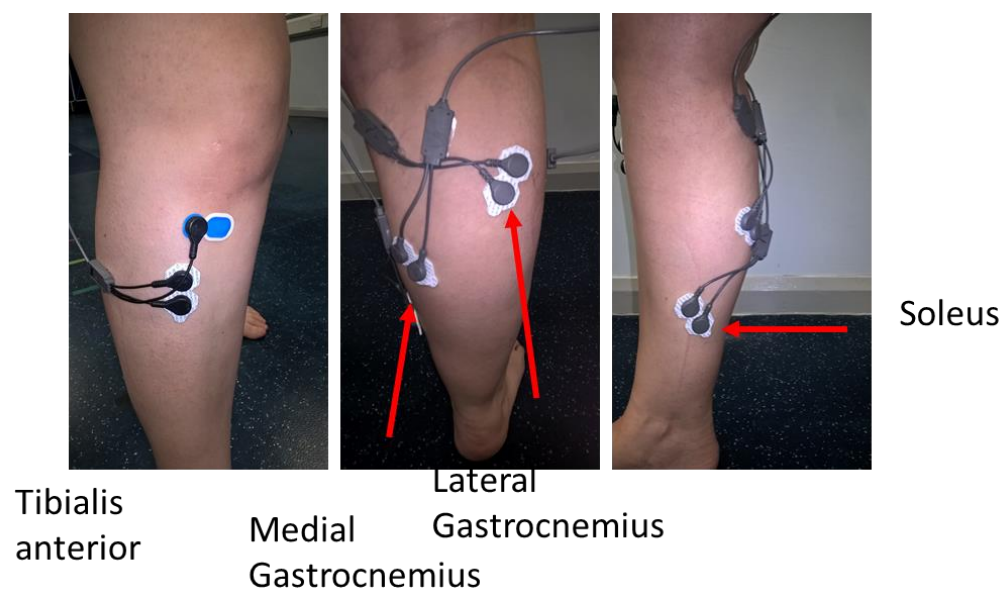


Figure 4.3: EMG electrode placement sites for the tibialis anterior, medial gastrocnemius, lateral gastrocnemius and soleus muscles.


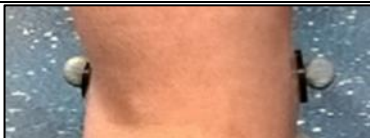





All measurements were taken by the same individual using the same measuring tape. All signals were checked within the Qualysis Track Manager (QTM) (Qualysis, AB, Gothenburg, Sweden) software for quality before continuing. Following the

verification check participants sat on a chair while the electrodes and cables were secured with bandages. These were placed loosely enough to ensure no signal contamination (due to noise) but securely enough so that the electrodes (NORAXON USA Inc.) and wires remained in place. Subsequently, participants were given a standardised pair of shoes, with a 20mm heel, to wear and reflective markers were placed on the upper and lower extremities as determined by the marker set-up in table below 4.2. Markers were always placed by palpation by the same individual (EE) to avoid inter-examiner error.

4.2.3.c Marker set-up

The CAST marker set-up was followed. Reflective markers with a diameter of 14.5 mm were used throughout the gait trials. These were attached to participants by using double sided, hypoallergenic adhesive tape. The shank and thigh segments were tracked respectively using clusters of 4 markers that were secured to the skin using double sided adhesive tape and super-wrap bandages. Finally, a neoprene belt with a marker cluster was wrapped around their waist to track the pelvis.

Table 4.2: Marker set up - segments defined, marker placement sites and names.

Foot	2 nd toe(2MT), 1 st (1DMT) and 5 th (5DMT) distal metatarsal head, 1 st (1PMT) and 5 th (5PMT) proximal metatarsal head, 3 heel markers (HEE, HEEL, HEER)	
Ankle	Medial and lateral malleolus (MMAL, LMAL)	
Shank	Cluster of 4 markers (Leg_1, Leg_2, Leg_3, Leg_4)	
Knee	Medial and lateral femoral tuberosity (Lknee, Mkee)	
Thigh	Cluster of 4 markers (thigh_1, thigh_2, thigh_3, thigh_4)	
Hip	Right and left greater trochanter (LTROC, RTROC)	
Pelvis	Left and right anterior superior iliac spine (L_ASIS, R_ASIS), left and right posterior superior iliac spine (L_P SIS, R_P SIS)	

5.2.3.d Static calibration

At the start of the data collection process, the participants were asked to stand stationary with their arms crossed on their chest for a static calibration of markers. While collecting data they were asked to step onto the first and subsequently 2nd force platform. The motion of the participants allowed false “ghost” markers to disappear as they are the ones that would have no traceable trajectory as the subject moved.

4.2.3.e Dynamic data collection

Having successfully captured all markers during the static data collection, participants were positioned at the top end of the room in a direction of travel in line with the force platforms. Participants were instructed to walk normally to the other side of the room, past the second set between two sets of timing gaits, along a 6.08m section of the lab, and to return to their initial position. As they walked, kinematic, kinetic and EMG data was captured. Data was collected at 100 Hz for kinematics, 200 Hz for kinetics and 1500 Hz for EMG. A walking trial was considered successful if the participant made contact with both forces plates with opposite feet during the same stride and with a walking velocity $\pm 5\%$ of their mean chosen walking speed, as calculated by five preliminary walking trials. If this was not the case, the trial was discarded. In order to ensure successful trials, the investigator moved the starting position of the participants accordingly. Data collection was completed when five successful walking trials were captured. Once data collection was complete, the markers and electrodes were taken off the participant and their weight and height were recorded using an electronic scale and a height measuring stand.

The procedures outlined above were repeated on each volunteer in the exact same sequence one week after the first data collection session. Both sets of results were then analysed.

4.2.3.f Kinematic and kinetic data processing

The trajectories of all reflective markers were identified in Qualysis track manager (QTM) (Qualysis, Gothenburg, Sweden). QTM software processes the signal and transforms the 2D kinematic files into a 3D image. All markers were then identified using a label list, created to correspond with the marker set-up (table 4.2). An automatic identification of markers (AIM) model was created for each individual using a dynamic trial of each participant. The AIM model identifies marker trajectories by saving the location (distance and angle) of the markers relative to one another. All files that were processed with the AIM model were subsequently checked for marker irregularities. These were fixed by cutting the marker trajectory just before and after the irregularity and deleting the data points containing the irregularity. The trajectory is amended by interpolation, using a built-in cubic spline algorithm. However, for the trajectory data to remain trustworthy, gap filling of irregularities in trajectories was kept to 10 frames or less. Data for each trial was then exported to c3d file format. These files were then input into Visual 3D (V3D) (figure 4.4) software (version 4.91, C-Motion Inc, Rockville, MD, USA). The physical body segments of each subject, as translated by the marker set-up used, were constructed as rigid body segments in V3D (rigid in that no motion within this segment is hypothesised) using motion tracking equipment. The collection of all segments comprises a V3D model. Each segment has a distinct position and orientation in 3D space, referred to as a pose (denoted by 3 variables to reflect position of segment origin; on the anterior-posterior, medial-lateral, vertical axes, and 3 to reflect rotation; in the sagittal, frontal and transverse planes). The ankle, knee and hip joint centres were computed and the foot, shank, thigh and pelvis segments were then created to complete the skeleton. Subsequently, moments and powers were calculated using the inertia data in visual 3D.

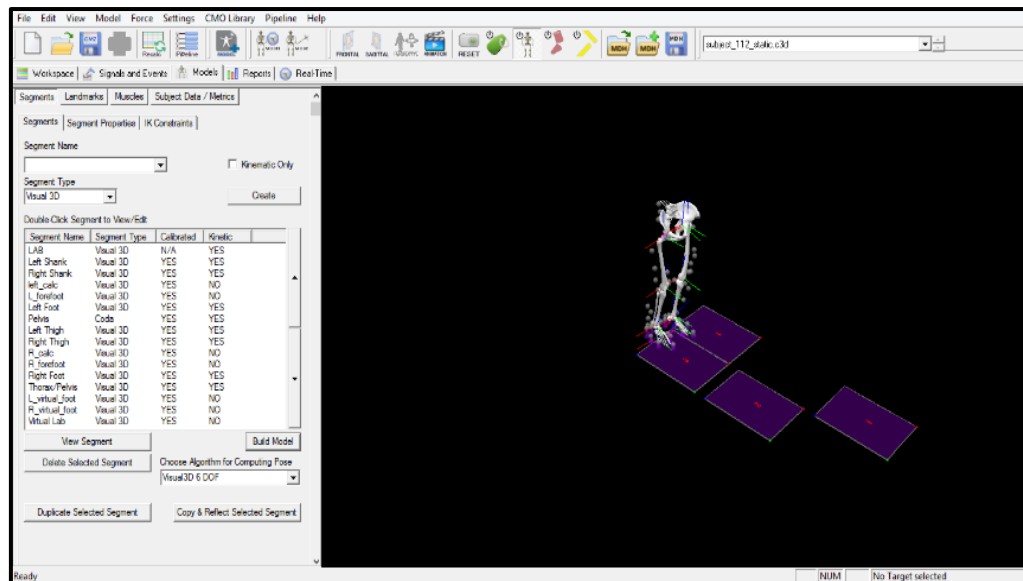


Figure 4.4: Visual 3D software, biomechanical model of the pelvis and lower limbs.

4.2.3.g Construction of the biomechanical model

Joints

Ankle joint

According to Lundberg et al (Lundberg et al., 1989), despite its polycentric movement, the ankle joint is always found close to the midpoint between the medial and lateral malleoli. Therefore, in the current study, the ankle joint centre was so identified by using the markers on the most prominent position of the medial and lateral malleoli and computing the centre of the linear segment whose edges are defined by the two markers.

Knee Joint

The knee joint was defined by identifying and placing markers at the medial and lateral femoral epicondyle of each leg. The joint centre was then automatically calculated in visual 3D and is defined as the midpoint between the medial and lateral knee markers.

Hip joint

The hip joint was defined using the CODA pelvis by Charnwood Dynamics using equations by Bell and Brand (Bell et al., 1990).

Segments

The foot

The foot segment was created using the ankle centre as a proximal landmark and the distal landmark was defined using the distal first and distal 5th metatarsal head. The segment was tracked using the 1st and 5th proximal and distal metatarsal head and the second MTP joint.

Foot Coordinate system

The coordinate system of the segment had an origin at the ankle joint centre, with an x-axis from the ankle centre to the midpoint between R1DMT and R5DMT, z axis perpendicular to the x-axis and the y axis perpendicular to x and y axes.

However, this model creates a foot at a plantigrade position relative to the shank, causing a 70 degree alteration to the ankle angle. To rectify this, a virtual foot was created which was used to create a segment coordinate system parallel to the floor and restore almost zero offset to the ankle. This was accomplished by distally transposing the ankle joint marker and the 1st and 5th metatarsal head markers, to the laboratory floor. In addition, the z-axis was aligned with the shank to create a vertical ankle as the ankle.

The shank

The shank segment was created using the knee centre as a proximal landmark and the ankle centre as a distal landmark and was tracked using a cluster of four markers on each leg, secured with double sided tape and bandages.

Shank coordinate system

The coordinate system of the shank had an origin at the knee joint centre, with the z-axis along the line of projection between the ankle joint centre and knee joint centre, the x-axis situated in the frontal plane orthogonal to the z-axis, and the y-axis perpendicular to the x- and z- axes.

The Thigh

The proximal anatomical markers for the thigh were the right and left greater trochanter accordingly and the hip joint centre as calculated by the CODA pelvis. The distal landmark used was the knee joint centre. The segment was tracked using a cluster of four markers, one on each leg, secured with double sided tape and bandages.

Thigh coordinate system

The coordinate system of the thigh has an origin at the hip joint centre, with the z-axis in the line of projection between the knee and hip joint centres, the x-axis, in the frontal plane, orthogonal to the z-axis and the y-axis perpendicular to the x- and z- axes.

The Pelvis

The pelvis was modelled using the markers placed on the right and left anterior and posterior iliac spine and the cluster of four markers that was placed at the lower back. This was secured to each participant with a neoprene belt that ensured a secure fit. The pelvis model used is the CODA pelvis by Charnwood Dynamics.

A pipeline to extract relevant outcome measures from the segment trajectories was created. The data were interpolated and low-pass filtered. Kinematic data was filtered with low pass 4th Order Butterworth filter (Robertson and Dowling, 2003), with a cut-off frequency of 12 Hz. Kinetic data and GRF data was low pass filtered with a cut-off frequency of 25 Hz (Robertson and Dowling, 2003).

4.2.3.h Computation of joint angles, moments, powers and ground reaction force (GRF):

Angles

Joint angles were defined as the orientation of the distal segment relative to the orientation of the proximal segment, using the coordinate system of the proximal segment. Therefore, ankle joint angle in the sagittal plane was defined by the angle

of the foot relative to the angle of the shank, using the coordinate system of the shank. Knee angle in the sagittal plane was defined by the angle of the shank relative to the angle of the hip, using the coordinate system of the hip (this is the internal angle between the posterior of the thigh and the posterior of the shank). Hip angle in the sagittal plane was defined by the angle of the thigh in relation to the angle of the pelvis, using the coordinate system of the pelvis.

Ground Reaction Force (GRF)

Ground reaction forces were calculated in vertical, anterior-posterior, and medial-lateral directions. Forces considered as positive were those from the ground up, anterior and medial reaction forces. Ground reaction forces were then normalised by body weight (body mass*9.81).

Moments

Joint moments were calculated using inverse dynamics analysis and moment calculations in visual3D, using the location, magnitude and direction of the external ground reaction force. This method calculates the net moments created at the muscles that move a joint and is applied under the assumption that muscles are the main controllers of motion at that joint. Moments were computed using Visual 3D software. Each limb was modelled as a rigid segment, with a local coordinate system in accordance with the pre-defined global coordinate system. Moments were calculated using the coordinate system of the proximal segment of each joint, by using x,y,z Euler Cardan sequences. Moments were then normalized by body mass.

Powers

Joint powers were calculated as the product of joint moment and angular velocity of the joint, using the power calculations within visual 3D.

4.2.3.i Post processing

The data was then exported into Matlab software for further processing and extraction of relevant parameters. In the current research these were: angles, moments, powers of the ankle knee and hip, as well as GRF data during stance for

each limb. The stance phase of gait was chosen as most pertinent to the current research as it is during this phase that the muscles of the calf are most active and reach peak activity. Therefore, outcome measures during the swing phase of gait were not analysed. For joint angles, moments and powers alike, data was presented from heel strike to toe-off on each foot. Therefore, the data was re-sampled to 101 points (representing 100% of stance) between heel strike and toe-off. Similarly GRF data was re-sampled to 100% of stance phase. Gait events were calculated automatically by the visual 3D software, using the data on heel strike, toe-off and consecutive heel strike of the leading limb from the force platforms. Second heel strike of the trailing limb was determined by use of a kinematic technique (Stanhope et al., 1990) whereby the software predicts the second heel strike of a limb based on the segment kinematics of the first heel strike that occurred on the force platform, using pattern recognition. The data for each curve was then ordered in Matlab and exported to excel (Microsoft Excel 2013). The mean peaks and troughs of trials for each outcome measure for each participant were calculated and assembled in Excel.

4.2.3.j EMG data collection and processing

EMG data was captured during data collection using the Noraxon TeleMyo system (TeleMyo 2400T G2 receiver, Noraxon U.S.A. Inc) (fig 4.5). The transmitter transmits the electrical signal that each muscle produces to the computer and straight into the Qualysis software where it is saved.



Figure 4.5: TeleMyo hardware used including left to right: wires which attach to electrodes, receiver box for the computer, transmitter to which electrode wires attach.

These signals were exported in their raw form to Matlab. Within Matlab the signals were full-wave rectified, high pass filtered at 20 Hz, low pass filtered at 500 Hz and then filtered using an RMS envelope with a time window of 80. The methodology of filtering and cut-off values were as indicated by DeLuca (2010). The signal was synchronised with the gait cycle, using a manual sync pulse which was activated during data collection. During Matlab processing, this pulse was used to synchronise the muscle signals with the duration of the gait cycle and the signal that was captured outside the gait cycle of interest was deleted. Matlab processing was made using a custom script. The relevant signal for each muscle was then exported to excel. Within excel the average mean was calculated for each muscle and all trials were normalised to this mean value for each muscle and each participant, during stance phase as in Burden & Barlett (1999). This method of normalisation was chosen over maximum voluntary contraction (MVC) so as not to tire out participants with PAD-IC at the beginning of the session and to ensure that the data collection session did not run any longer than needed. Since the sessions were estimated to take an average of three hours to complete, adding time to perform MVCs would likely have deterred many from completing the full session.

For this reason, normalisation to the mean signal, which is less prone to artefact than the peak signal, was chosen as the normalisation method.

Following normalisation, the maximum values for the five normalised trials for each EMG signal (for each of the muscles) for each participant was computed as the mean of maximums of the five trials processed.

4.2.4 Statistical analysis

The ICCs were interpreted according to the grading suggested by Coppieters (2002). The SEM was calculated as follows: $SD \text{ (pooled)} * \sqrt{1 - ICC}$ (Thomas, 2011). In order to determine the minimum change between two measurements, minimal detectable difference (MDD) was calculated as follows: $1.96 * SEM * 1.4142$ (Kean et al., 2010).

4.2.5 Results

The table below (table 4.3) shows ICC for maximum ankle, knee and hip, angles, moments and powers in the sagittal plane in late stance, GRF data maxima in all planes and peak EMG activity of the medial and lateral gastrocnemius, soleus and tibialis anterior muscles. ICC values are presented for all outcome measures that will be considered in the studies in chapters 5-7. SEM and MDD values are only presented (tables 4.4, 4.5) for ankle angles, moments and powers in the sagittal plane as well as the peak EMG activity of the aforementioned muscles. The reason for this is that changes at the ankle and calf are the most pertinent to the current research and ankle moment and power are the main outcome measures of the study.

Table 4.3: ICC values for maximum ankle, knee and hip angle and external moment and maximum GRF in late stance, in the anterior, sagittal and coronal planes for the left and right lower limbs

	Left	Right
Maximum ankle dorsiflexion angle	0.98	0.95
Maximum knee angle extension angle	0.96	0.98
Maximum hip angle extension angle	0.87	0.93
Maximum external ankle dorsiflexion moment	0.99	0.99
Maximum external knee extension moment	0.96	0.83
Maximum external hip extension moment	0.93	0.98
Maximum anterior GRF	0.99	-
Maximum lateral GRF	0.95	-
Maximum vertical GRF	0.99	-
Maximum anterior GRF	-	0.99
Maximum medial GRF	-	0.90
Maximum vertical GRF	-	0.98

Table 4.4: SEM and MDD values (in °, Nm/Kg and W/Kg accordingly) for the maximum right ankle and knee angles, external moments and powers (late stance) in the sagittal plane.

	SEM	MDD
Maximum ankle dorsiflexion angle	1.32	3.67
Maximum external ankle dorsiflexion moment	0.05	0.15
Maximum ankle power generation	0.16	0.45
Maximum knee extension angle	1.08	3.00
Maximum external knee extension moment	0.02	0.06
Maximum knee power absorption	0.04	0.12

Table 4.5: ICC, SEM and MDD values for peak EMG activity (normalised by mean activity, during stance phase) for tibialis anterior, medial gastrocnemius, lateral gastrocnemius and soleus, for the left and right leg in the sagittal plane

	Left			Right		
	ICC	SEM	MDD	ICC	SEM	MDD
Peak Tibialis Anterior activity	0.74	0.15	0.42	0.56	0.12	0.34
Peak Medial Gastrocnemius activity	0.95	0.15	0.42	0.93	0.17	0.48
Peak Lateral Gastrocnemius activity	0.74	0.17	0.48	0.94	0.21	0.58
Peak Soleus activity	0.96	0.17	0.46	0.98	0.17	0.48

4.2.6 Discussion/ Conclusion

ICC values for all main outcome measures (ankle moment and power) are above 0.8 denoting good to excellent repeatability. These results are in accordance with previous studies although most of these have used the Helen Hayes marker set (Andrews et al., 1996, Kadaba et al., 1989, Growney et al., 1997, Tsushima et al., 2003). Groney et al (1997) also tested repeatability between sessions and found excellent repeatability in the sagittal plane. Collins et al (2009) measured ICC values using the modified Helen Hayes marker set and report ICC values for max dorsiflexion and plantarflexion during stance. Their results are 0.91 and 0.98 accordingly and are described as very good for the purposes of the study. Maximum flexion and extension angles for the knee achieved ICC values of 0.3 and 0.9 accordingly (Collins et al., 2009). Kadaba et al (1989) report high repeatability for the medial gastrocnemius and tibialis anterior muscles with CMC values above 0.8 both for with day and between day repeatability. In the present study kinematic, kinetic, GRF and EMG results remained in the range of good to excellent ensuring the validity of the results of the main study. As discussed above, the minimally detectable differences denote that any changes observed in the outcome parameters, above the denoted MDD figures, can be considered true alterations in gait biomechanics. It is understood and expected that repeatability in young healthy individuals is lower than repeatability in older individuals and more so in individuals with PAD-IC, who have a significantly more variable gait (Crowther et al., 2008, Myers et al., 2009). However, the present repeatability study was undertaken with the aim to assess the repeatability of the individual conducting the study, not the repeatability of the study population.

Chapter 5. The effects of PAD-IC on gait

5.1 Introduction

Use of footwear or orthotics to modify the mechanical workload of the calf muscles may allow for the increase in pain free walking distance and daily activity of individuals with PAD-IC, hence increasing their quality of life. **However, to design footwear to alter calf muscle activity in these individuals, it is first required to have a complete understanding of gait in patients with PAD-IC.** This chapter investigates the characteristics of PAD-IC gait compared to age-matched healthy individuals. The recruitment method and study methodology are firstly outlined. These are followed by the study results and a discussion of the findings as they relate to previous research and to the fulfilment of the current research objectives. The results of this study will be used to interpret the findings in the next chapter and to identify the most effective intervention.

5.2 Aim

To investigate the differences in gait kinematics, kinetics and muscle activation patterns between individuals with PAD-IC (during pain-free walking) and healthy and age-matched controls. Specific hypotheses were not made in advance as the purpose of this study was to investigate the effects of the condition and to compare with prior findings.

5.3 Methods

5.3.1 Participant recruitment, inclusion and exclusion criteria

Recruitment

Participant recruitment received approval from the University ethics committee (Number HSCR13/91) and the NHS Brighton and Sussex NRES Committee (study

number: 14/LO/0382). Approval from the University ethics committee is a prerequisite for all research conducted at the University of Salford and any recruitment of NHS patients requires the approval of the corresponding study by an NHS appointed ethics committee. Participants with PAD-IC were recruited from the Wrightington, Wigan and Leigh NHS Trust and from Salford Royal Hospital, the Trust podiatry clinics in Salford and exercise program in Walkden (Manchester). In each case the vascular surgeon who met the patient or the vascular podiatrist whose exercise program patients were referred to, assessed the patient's condition and medical history versus the study inclusion criteria (outlined in the sections below). If they found the patient was eligible for the study they offered them an information pack containing an invitation letter, the study information sheet and a data access form. In brief, they explained the purpose of the study and what it entailed and explained to patients that, were they interested in participating they had one of two options: a) read through the form on their own and contact the research team in their own time via the contact information provided, b) complete the data access form and leave it with the NHS partner who would hand it over to the research team. The team would then make contact with the patient after the passing of 24 hours to discuss the study, answer questions and ask whether the patient would be interested in taking part. If at any point the patient expressed unwillingness to take part no further contact was made by the research team.

The researcher was also allowed to be present in several exercise classes and answered patient questions regarding the study if prompted. However, no personal or contact information were passed to the researcher at these times, to allow patients a 24-hour window to consider the study freely and without coercion. Following is an outline of the recruitment methods used for individuals with PAD-IC participants (fig 5.1).

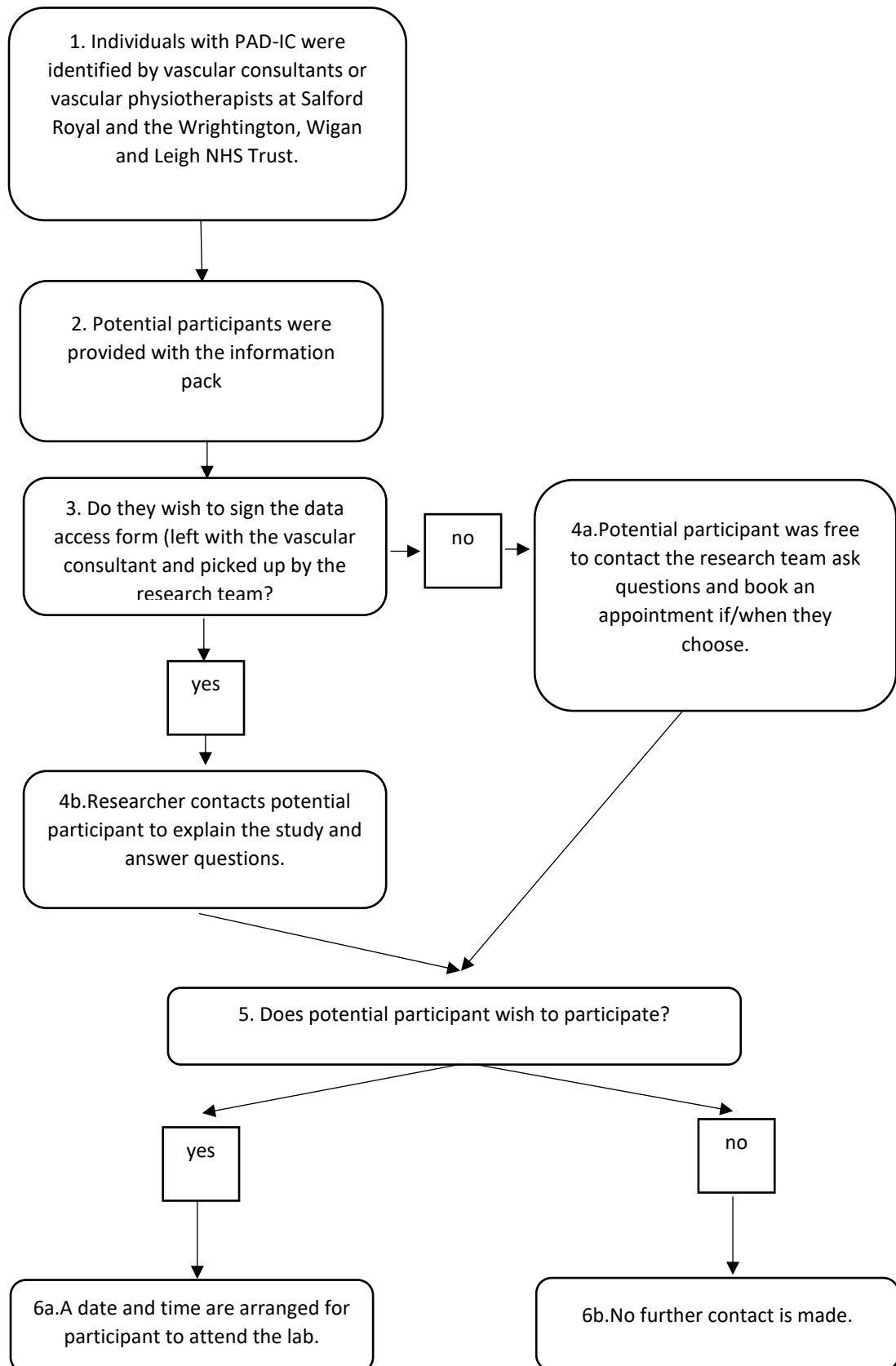


Figure 5.1: Recruitment method – participants with PAD-IC

Healthy individuals were recruited into the study through posters set up at the university and the hospitals and clinics outlined above. If an individual was interested in taking part they contacted the research team to arrange a date and time. Following is an outline of the recruitment methods used for healthy participants (fig 5.2).

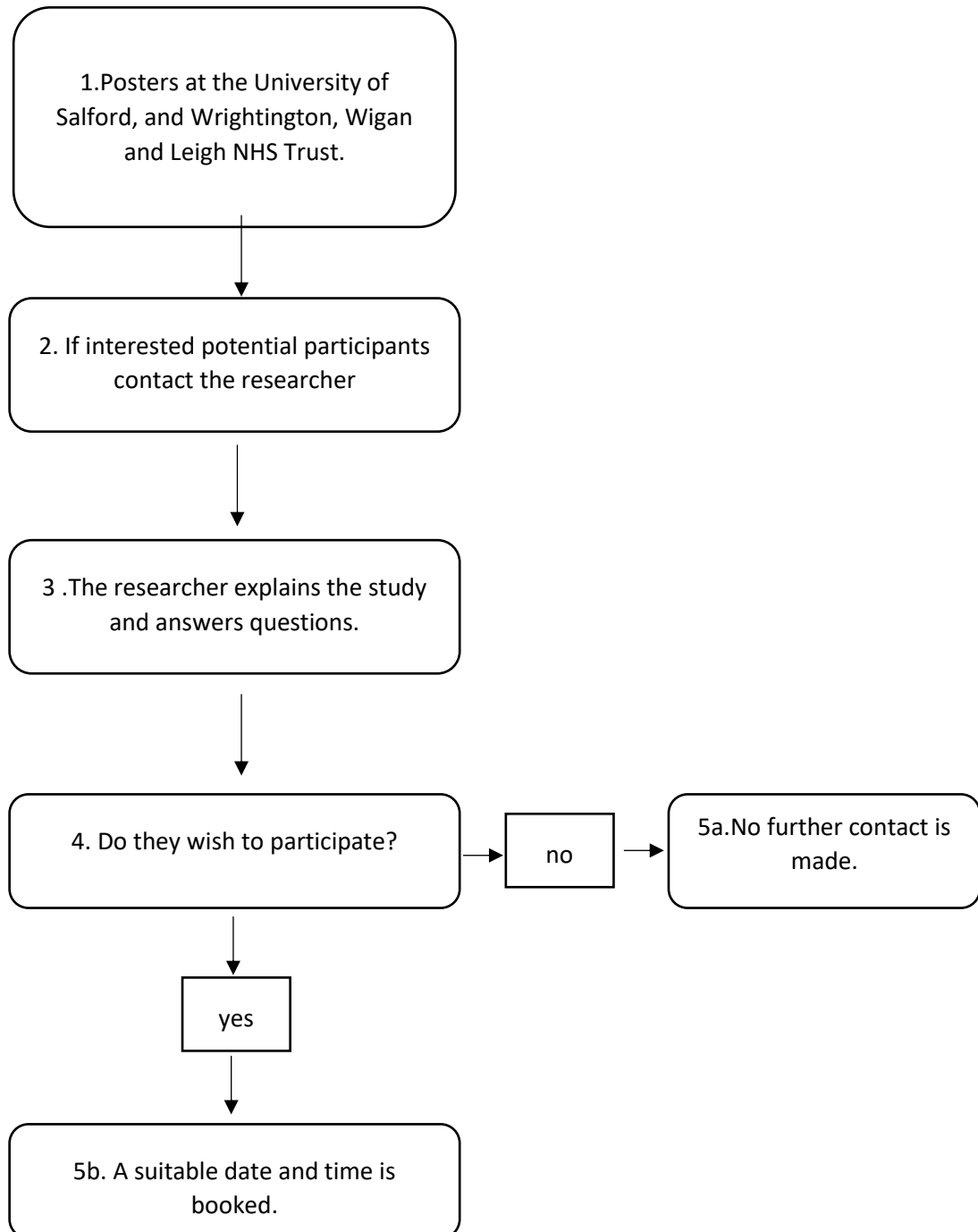


Figure 5.2: Recruitment method healthy participants

Inclusion criteria

Participants aged 50 or older with a diagnosis of intermittent claudication by a consultant vascular surgeon were admitted into the study. This was confirmed, by authorised medical personnel, using colour-flow duplex scan, medical history and examination, and absence or reduction in foot pulses and an ankle brachial pressure index (ABPI) of less than 0.8. In all cases ABPI was measured either by the vascular surgeon or a specialised vascular physiotherapist as part of the diagnosis procedure of the individual with PAD-IC. Participants were self-reported able to walk a minimum of 100m, on level over ground terrain not treadmill testing, or perform two minutes of continuous walking unaided. Both individuals with uni-lateral and individuals with bi-lateral PAD-IC were accepted into the study. In the case of bi-lateral participants data from the self-reported worst leg (i.e the one that hurt first when walking) was used. This was not necessarily the leg with the lowest ABPI. Individuals with diabetes but diagnosed free of diabetic neuropathy were also accepted in the study. Self-reported healthy controls matched for age were also admitted into the study. A sample size of 18 patients and 18 healthy controls were used. Controls were matched to individuals with PAD-IC for age.

Exclusion criteria and sample size

Individuals with PAD-IC were excluded if they had active or a prior history of foot ulcers, significant foot deformities (e.g. self-reported club foot, amputated toes/part of foot; fallen arch, excessive pronation and similar conditions were not excluded), neuropathy in their feet, recent surgery, pain in their lower limbs or back with a cause unrelated to PAD-IC, painful knee, ankle or hip osteoarthritis, total reliance on walking aids, prior lower limb joint replacement, or were morbidly obese (BMI>35). These criteria were evaluated by authorised medical personnel (at the time of making individuals aware of the study). Finally, individuals with other gait altering chronic illnesses, such as Parkinson's and neuromuscular disorders were also excluded from the study.

Control participants were excluded if, when asked by the researcher, they reported any of the following: significant pain in the legs when walking, prior injury to the

legs or spine, diabetic neuropathy, foot deformities (e.g. club foot, amputation of toes), prior joint replacement or major orthopaedic surgery.

A priori-power calculations, using peak ankle moment in late stance as primary outcome measure, indicated that a sample size of 17 individuals in each group were required (power of 0.8). A sample size of 23 was required to achieve a power of 0.8 in the second main outcome measure (ankle power in late stance) for a two-tailed design. The effect sizes for the calculation were computed using data from Koutakis et al (2010a). Due to difficulties with participant recruitment, and despite use of several recruitment strategies, only 18 individuals with PAD-IC and 18 healthy controls were recruited. (However, post-hoc power calculations on the main outcome measures indicated powers of 0.84 and 0.98 respectively, indicating that the study had sufficient power to support the findings).

5.3.2 Data collection

Eighteen individuals with PAD-IC and 18 healthy controls took part in the study. Participant characteristics can be found in table 5.1 below.

Table 5.1: Participant characteristics

	Healthy	PAD-IC	P value
Male	11	12	n/a
Female	7	6	n/a
Mean Age (y) (kg*g)	64.0(9.2)	67.5(7.9)	0.246
Mean Height (m)	1.65 (SD = 0.08)	1.70 (SD = 0.08)	0.422
Mean mass (kg)	69.2 (SD = 10.6)	75.3 (SD = 12.4)	0.182
Diabetes	0	2	n/a
Unilateral claudication	n/a	7	n/a
Bi-lateral claudication	n/a	11	n/a
Claudication level	n/a	Levels 2, 3 Rutherford scale	n/a

Participants who attended the lab sessions were asked to read through and, if in agreement, sign the consent form. They were then shown to the changing room to change into their shorts and top. When this was done participants lay on a medical bed and the gel electrodes were placed on the tibialis anterior, medial and lateral gastrocnemius and soleus muscles of each leg. The placement of electrodes and preparation of placement sites is described in sections 4.1 and 4.2.3.b. The electrodes were connected to a transmitter box via wires and the transmitter box was secured on a neoprene vest that individuals wore.

Reflective markers were then placed on the lower limbs and torso of each participant as depicted in the figure below (fig 5.3). All markers placed are detailed in section 4.2.3.c. Participants completed trials in a pair of bespoke, Oxford style shoes in their chosen size, provided by the research lab.



Figure 5.3: Marker set up - an explicit analysis of the setup used can be found in chapter 4, section 4.2.3.c.

Motion data was collected using Qualisys software (Qualisys AB, Gothenburg, Sweden) at 100Hz. EMG data was captured using the wired Noraxon (TeleMyo 2400 G2, Scottsdale, Arizona 85260) system. Participants first stood in the middle of the capture volume, on one of the force plates, so as to collect a static calibration trial for kinematic modelling and to define zero degrees.

Participants were then asked to walk, in a straight line across a 6.08m section of the lab. At the beginning and end of the section timing gates were placed to collect walking speed data. Participants were first asked to walk from before the first set of timing gates to after the second set for five times in order to compute their average speed. Average speed was computed using a Matlab script which also computed a 5% window on either side of the average. Following this, participants were asked again to walk across the lab section, in the same manner, as kinematic, kinetic, temporal-spatial and EMG data was collected. Once five successful walks had been collected the markers and electrodes were taken off and participants' height and weight was measured. A walk was considered successful when the EMG signal for all four muscles was of recorded successfully, all the markers where visible by the Oqus cameras, both feet made contact with the force plates, and participants remained within $\pm 5\%$ of their average speed. In the case of individuals with PAD-IC a walk was considered successful if the most affected limb, (self-reported) made contact with the force plate.

5.3.3 Data analysis

Data was analysed in Visual 3D (version 6.0, C-Motion Inc, Rockville, MD, USA) according to the method outlined in sections 4.2.3.f – 4.2.3.h & 4.2.3.j. In the current research outcome measures studied were: maximum and minimum angle, moment, and power of the ankle, knee and hip of the stance limb as well as peak ground reaction force in the anterior-posterior, medial-lateral and vertical direction. For individuals with PAD-IC the most affected limb (the one indicated by participants as the one that hurt first when walking) was used for comparison. In

healthy controls the limb used for the comparison was chosen randomly. The data was then exported into Matlab software for further processing and extraction of outcome measures (section 4.2.3.i). Data was then re-organised in Matlab and exported to excel (Microsoft Excel 2013). Within Excel the maxima and minima of outcome measures throughout stance were calculated for each trial and averaged for each participant. EMG signals were exported from QTM in their raw form to Matlab and analysed according to section 4.2.3.j. These were then exported to excel (Microsoft Excel 2013). In the exact same manner as in chapter 4, each participant's data for each muscle was normalised to the mean EMG activity for that muscle, during stance phase of gait. The maximum value for each normalised EMG signal (for each of the muscles) for each participant was computed as the mean of maximums of the five trials processed.

5.4 Statistical analysis

The difference in means between individuals with PAD-IC and healthy controls for all outcome measures, were investigated using independent sample t-tests (alpha level = 0.05) in SPSS (Version 23, IBM Corporation). If data were found not to follow a normal distribution (normality test SPSS) the non-parametric Wilcoxon test was used instead.

With regard to EMG data, because each subject's signals, for each muscle, were normalised to the average mean for that muscle, a further step was needed to ensure comparison of two groups of individuals was valid. This was because the mean muscle activity of each group could be assumed to be different and therefore the measures of muscle activity would be, in effect, on different scales.

As an example, we assume that:

- Peak tibialis anterior EMG activity for Controls is 3.4 times the mean of the control group
- Peak tibialis anterior EMG activity for PAD-IC is 2.8 times the mean the individuals in that group

and that this difference is found to be significant. However, the means of the 2 groups will be different and the values 3.2 and 2.8 are not values of the same scale. Therefore, the un-normalised means will also be presented in the results.

Following the t-tests, the results were also adjusted for speed, by conducting a univariate analysis of variance and choosing speed as a co-variate. This is a method of statistically accounting for the effect that speed has on each outcome measure by taking out the variance that speed accounts for in the calculation. The speeds of all participants both PAD-IC and healthy are therefore taken into account in this calculation.

5.5 Results

Kinematic, kinetic and temporal-spatial data was collected on 18 individuals with PAD-IC and 18 age-matched healthy controls were tested as part of this study (table 5.2). EMG data was successfully collected on 13 of the individuals with PAD-IC and 13 healthy age-matched controls. In the remaining participants, data was either not deemed to be acceptable, or not collected due to EMG system failure. Following is a detailed description of the study results.

Both average speed ($p = 0.000$) and step length ($p = 0.019$) were found to be significantly reduced for individuals with PAD-IC compared to healthy age matched controls (table 5.2). Power data has been labelled on figures and in text according to bursts for each muscle in chronological order. The burst labels used by Winter et al (1995) are not used as more peaks and troughs are analysed in the present research.

Table 5.2: Participant temporal-spatial parameters.

	Healthy	PAD-IC	P value
Mean Walking Speed (m/s)	1.25 (SD = 0.23)	1.00 (SD = 0.25)	0.000
Step length (m)	0.71m (SD = 0.13)	0.62m (SD = 0.07)	0.019
Stance time	0.68(SD=0.07)	0.77(0.13)	0.030
Double support time	0.26(0.05)	0.27(0.08)	0.708
Cadence	109(SD=8.80)	97(SD=9.07)	0.001

Ankle

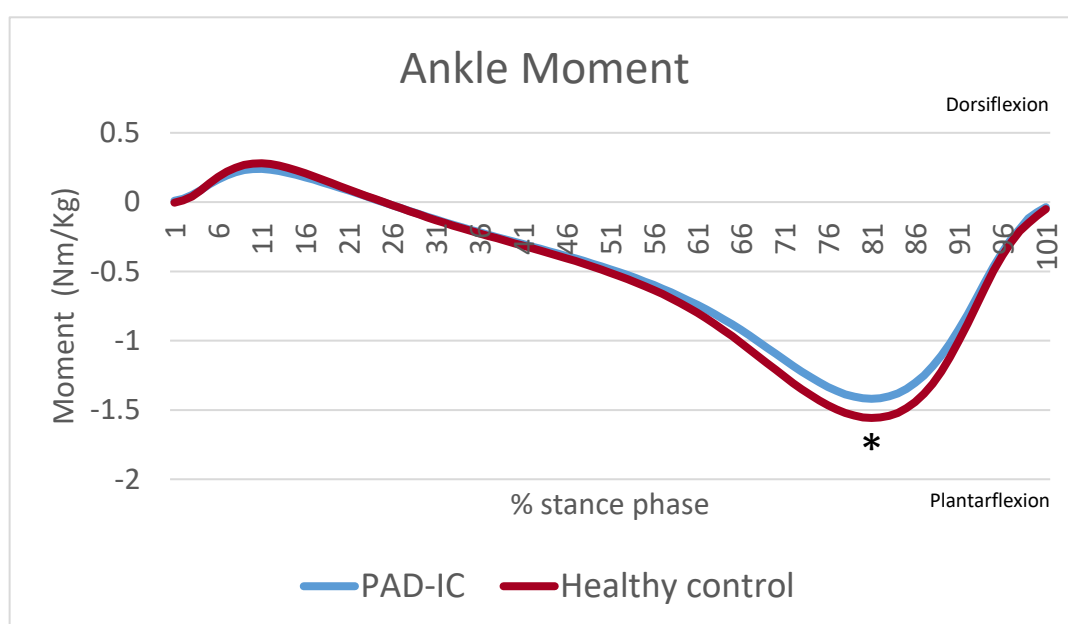


Figure 5.4: Internal ankle plantarflexion moment for PAD-IC and healthy controls during stance. Significant differences indicated with an asterisk.

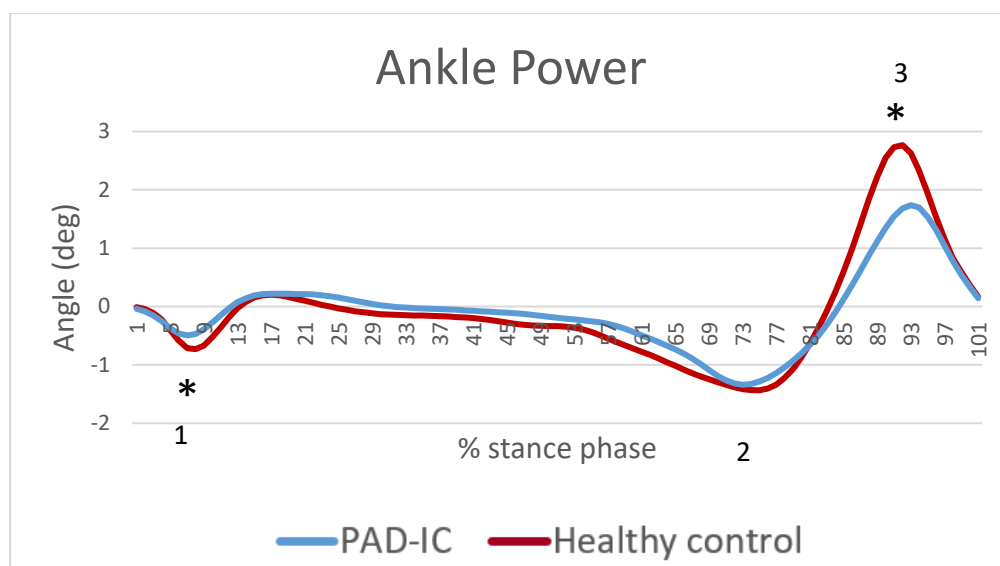


Figure 5.5 Ankle power for PAD-IC and healthy controls during stance. Significant differences indicated with an asterisk.

Maximum ankle plantarflexion and dorsiflexion were not significantly different in individuals with PAD-IC compared to controls ($p=0.081$), ($p=0.559$). No significant differences were identified for internal ankle dorsiflexion moment in early stance ($p=0.270$) (table 5.3) (fig 5.4). Internal ankle plantarflexion moment in late stance was significantly reduced in individuals with PAD-IC compared to controls ($p=0.006$).

Ankle power was found to be significantly reduced individuals with PAD-IC both in early ($p=0.018$) stance (burst 1) and late stance (burst 3) ($p=0.000$). Ankle power in mid-stance (burst 2), did not differ significantly between PAD-ICs and controls. These findings are also presented in table 5.3 (fig 5.5).

When adjusting for speed only internal ankle plantarflexion moment and ankle power in late stance remained significantly different ($p = 0.030$; $p = 0.022$) and speed did not explain a significant amount of the variance ($p = 0.241$; $p = 0.092$).

Table 5.3: Mean peaks, standard deviation and p values for individuals with IC and healthy controls at the ankle.

Outcome measure	Mean PAD-IC	SD	Mean Control	SD	Significance p	t	df	Effect size
Max ankle plantarflexion (°)	-5.69	2.82	-7.23	2.29	0.081	1.796	35	0.60
Max ankle dorsiflexion (°)	19.5	3.14	18.9	3.18	0.559	0.590	35	0.19
Max internal ankle dorsiflexion moment early stance (Nm/Kg)	0.25	0.11	0.28	0.07	0.467	-1.23	35	0.33
Max internal ankle plantarflexion moment late stance (Nm/Kg)	1.41	0.15	1.55	0.14	0.004	3.059	35	0.96
Max ankle power absorption early stance (W/Kg)	-0.55	0.26	-0.76	0.25	0.018	2.477	35	0.82
Max ankle power absorption mid-stance (W/Kg)	-1.29	0.27	-1.57	0.66	0.112	1.653	22.526	0.56
Max ankle power generation late stance (W/Kg)	1.90	0.49	2.80	0.80	0.000	-4.032	35	1.36

Knee

At the knee, the internal flexion moment in individuals with PAD-IC was found to be significantly reduced at initial contact ($p=0.009$), but internal extension moment in early stance, flexion moment in late stance and extension moment in terminal stance ($p=0.184$, $p=0.354$, $p=0.136$) were equivalent to healthy counterparts (fig

5.6). Knee power absorption was reduced both in early stance (burst 2, fig 5.7) and late (burst 4, fig 5.7) in individuals with PAD-IC ($p=0.001$) ($p=0.002$). Knee power generation in mid-stance was also significantly reduced (burst 3, fig 5.7) ($p=0.047$). Maximum knee flexion in early stance and extension in late stance did not differ significantly between groups ($p=0.350$) ($p=0.986$). These findings are also presented in table 5.4.

When adjusting for speed only knee power absorption in early stance (burst 2, fig 5.7) was found to be significantly reduced compared to controls ($p = 0.022$). Walking speed did not explain a significant amount of the variance ($p = 0.225$).

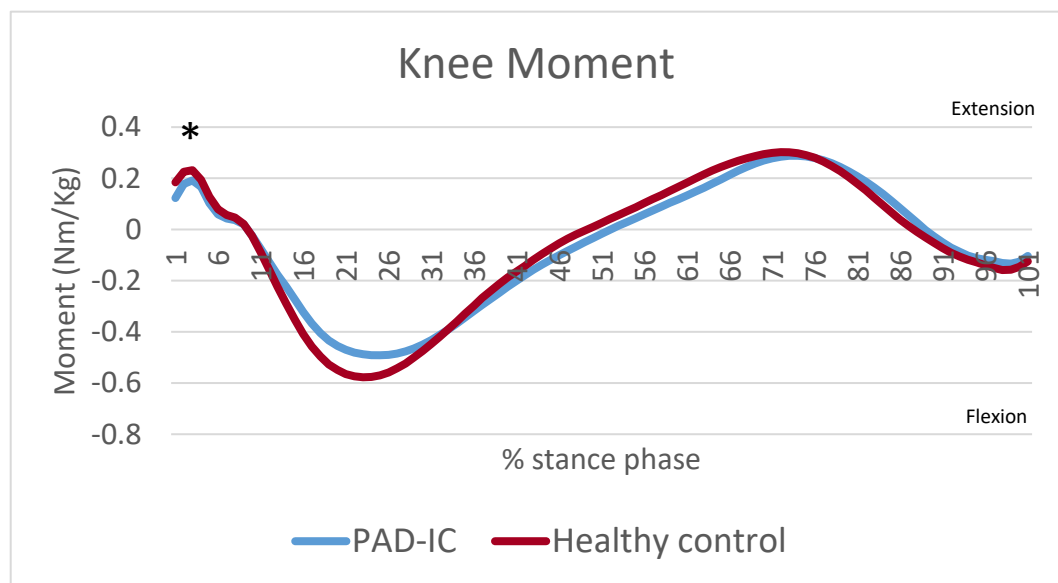


Figure 5.6: Internal knee moment of individuals with PAD-IC and healthy controls during stance. Significant differences indicated with an asterisk.

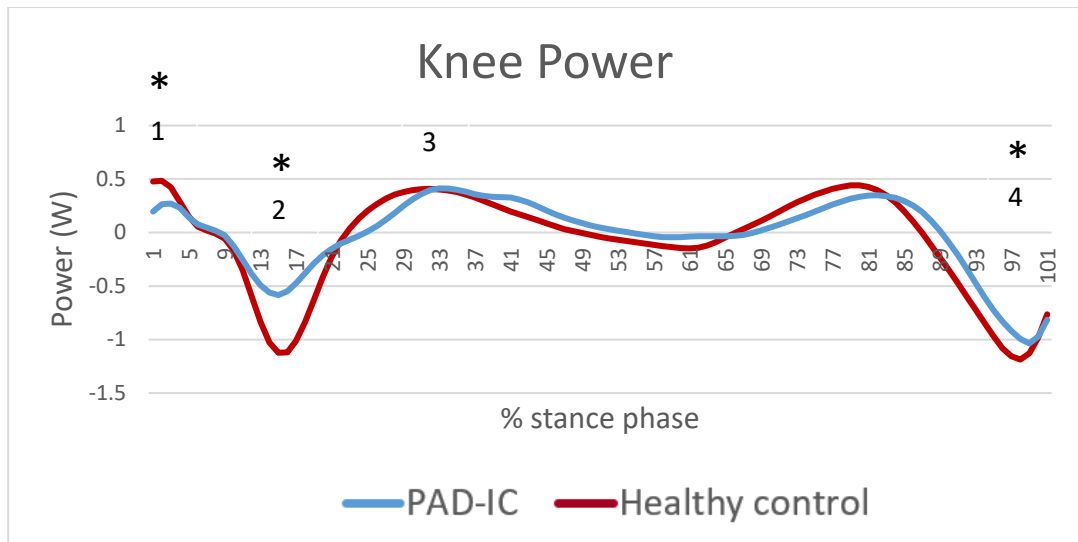


Figure 5.7: Knee power of individuals with PAD-IC and healthy controls during stance. Significant differences indicated with an asterisk.

Table 5.4: Mean peaks, standard deviation and p values for individuals with IC and healthy controls at the knee.

Outcome measure	Mean PAD-IC	SD	Mean Control	SD	Significance p	t	df	Effect size
Max knee flexion early stance (°)	15.29	5.31	16.99	5.46	0.81	2.76	35	0.32
Max knee extension (°)	3.13	4.66	3.10	5.71	0.559	1.883	35	0.01
Max internal knee flexion moment initial stance (Nm/Kg)	-0.18	0.08	-0.25	0.08	0.009	-2.772	35	0.88
Max internal knee extension moment early stance (Nm/Kg)	0.50	0.22	0.59	0.19	0.184	-1.356	35	0.44
Max internal knee flexion moment late stance (Nm/Kg)	-0.30	0.12	-0.33	0.11	0.354	0.939	35	0.26
Max internal knee extension moment terminal stance (Nm/Kg)	0.15	0.06	0.18	0.06	0.136	1.528	35	0.50
Max knee power absorption early stance (W/Kg)	-0.54	0.40	-1.03	0.38	0.001	3.757	35	1.26
Max knee power generation (W/Kg)	0.53	0.22	0.52	0.26	0.047	-2.064	35	0.04
Max knee power generation mid-stance (W/Kg)	0.40	0.13	0.49	0.23	0.147	-1.486	35	0.48
Max knee power absorption late stance (W/Kg)	-0.81	0.33	-1.15	0.31	0.002	3.269	35	1.06

Hip

At the level of the hip, the internal moment was reduced for individuals with PAD-IC, compared to controls, both in early and late stance (fig 5.8). Hip power absorption in early stance (burst 1, fig. 5.9) and hip power generation (burst 2, fig 5.9) in early stance were also significantly reduced for individuals with PAD-IC

compared to controls ($p=0.000$) ($p=0.024$). Hip power absorption in mid-stance (burst 3, fig. 5.9) was not statistically different between groups ($p=0.482$) (fig 5.8).

Maximum hip extension in mid-stance ($p=0.810$) and hip flexion in early stance ($p=0.922$) and did not differ significantly between groups. No significant changes in power production were observed in late stance (burst 4, fig 5.9) ($p=0.136$). These findings are also presented in table 5.5.

When adjusting for speed only hip power absorption in early stance (burst 1, fig. 5.9) was found to be significantly reduced compared to controls ($p = 0.000$). Speed did not explain a significant amount of the variance ($p = 0.372$).

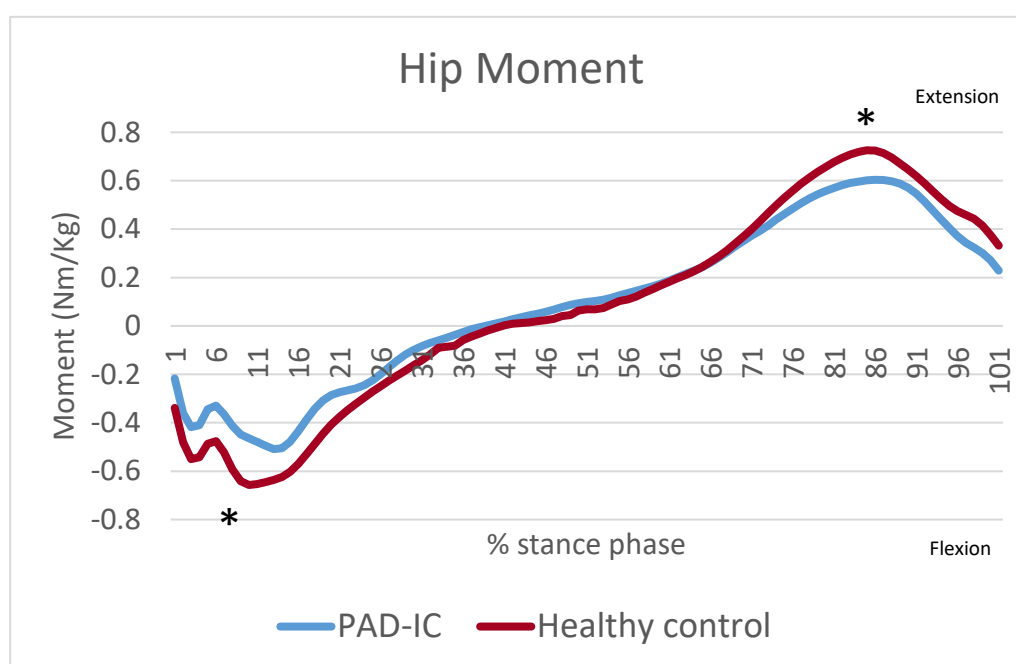


Figure 5.8: Internal hip moment of individuals with PAD-IC and healthy controls during stance. Significant differences indicated with an asterisk.

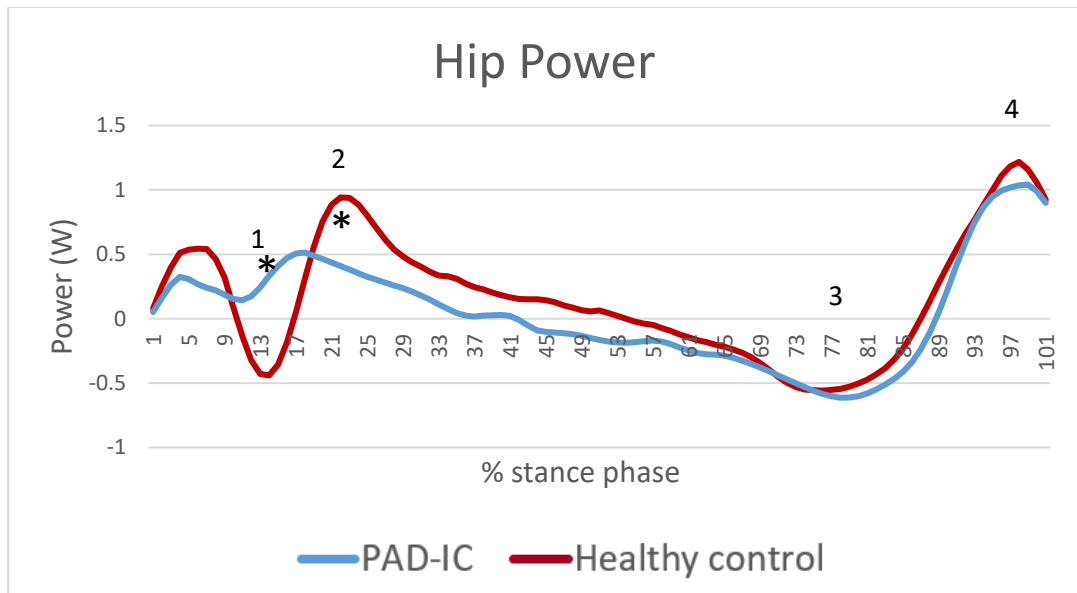


Figure 5.9: Hip power of individuals with PAD-IC and healthy controls during stance. Significant differences indicated with an asterisk.

Table 5.5: Mean peaks, standard deviation and p values for individuals with IC and healthy controls at the hip.

Outcome measure	Mean PAD-IC	SD	Mean Control	SD	Significance p	t	df	Effect size
Max hip flexion (°)	34.87	9.67	35.17	8.33	0.922	-0.98	35	0.03
Max hip extension (°)	-5.66	11.47	-6.55	10.65	0.810	0.242	35	0.08
Max internal hip extension moment early stance (Nm/Kg)	-0.55	0.16	-0.74	0.25	0.012	-2.671	35	0.90
Max internal hip flexion moment late stance (Nm/Kg)	0.61	0.19	0.77	0.25	0.032	2.239	35	0.72
Max hip power generation early stance (Nm/Kg)	0.52	0.26	0.85	0.53	0.024	-2.403	35	0.79
Max hip power absorption early stance (W/Kg)	-0.09	0.22	-0.52	0.28	0.000	5.065	35	1.07
Max hip power generation late stance (W/Kg)	0.98	0.35	1.18	0.43	0.136	-1.528	35	0.51
Max hip power absorption late stance (W/Kg)	-0.62	0.44	-0.72	0.37	0.482	0.711	35	0.25

EMG

The maximum EMG activity during stance was reduced for the lateral gastrocnemius (by 22%) and soleus (by 19%) muscles in participants with PAD-IC compared to controls ($p = 0.016$, $p = 0.010$) (table 5.6, 5.7, fig 5.12, 5.13). After adjusting for speed only soleus activity remained significantly reduced compared to controls (adj. means Healthy: 3.58, PAD-IC: 2.67; $p = 0.026$).

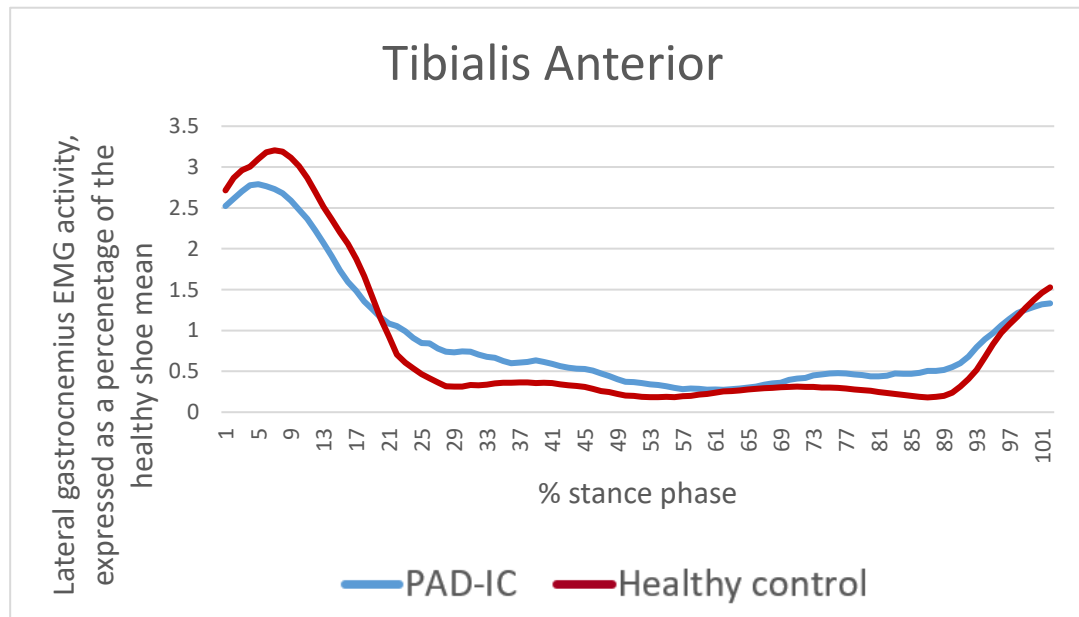


Figure 5.10: Tibialis anterior activity in individuals with PAD-IC and healthy controls. Peaks are expressed as a percentage of each group's mean. Significant differences indicated with an asterisk.

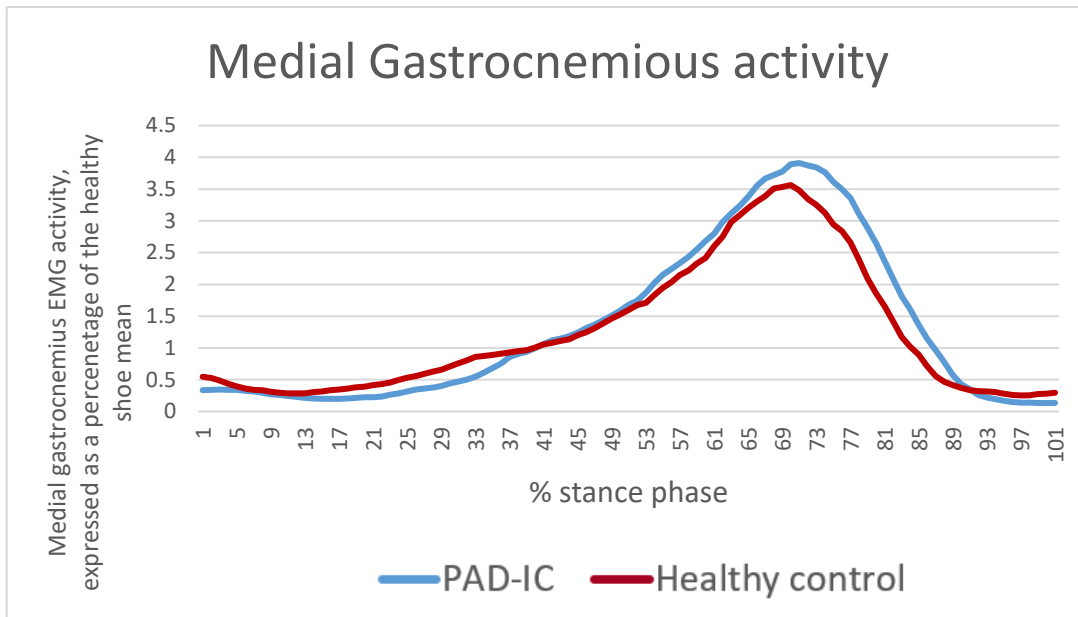


Figure 5.11: Medial gastrocnemius activity in individuals with PAD-IC and healthy controls. Peaks are expressed as a percentage of each group's mean. Significant differences indicated with an asterisk.

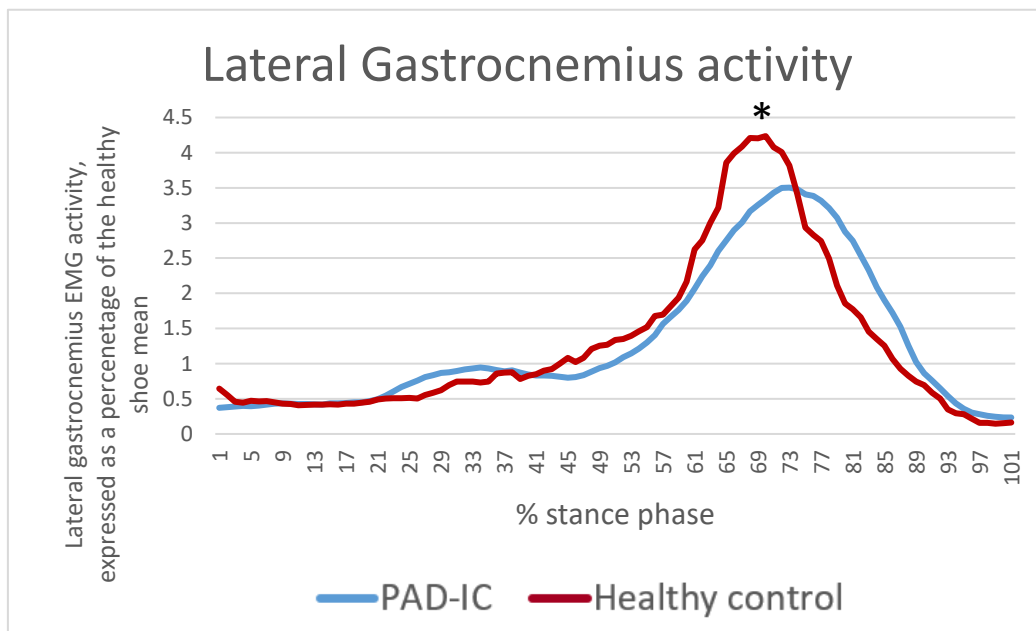


Figure 5.12: Lateral gastrocnemius activity in individuals with PAD-IC and healthy controls. Peaks are expressed as a percentage of each group's mean. Significant differences indicated with an asterisk.

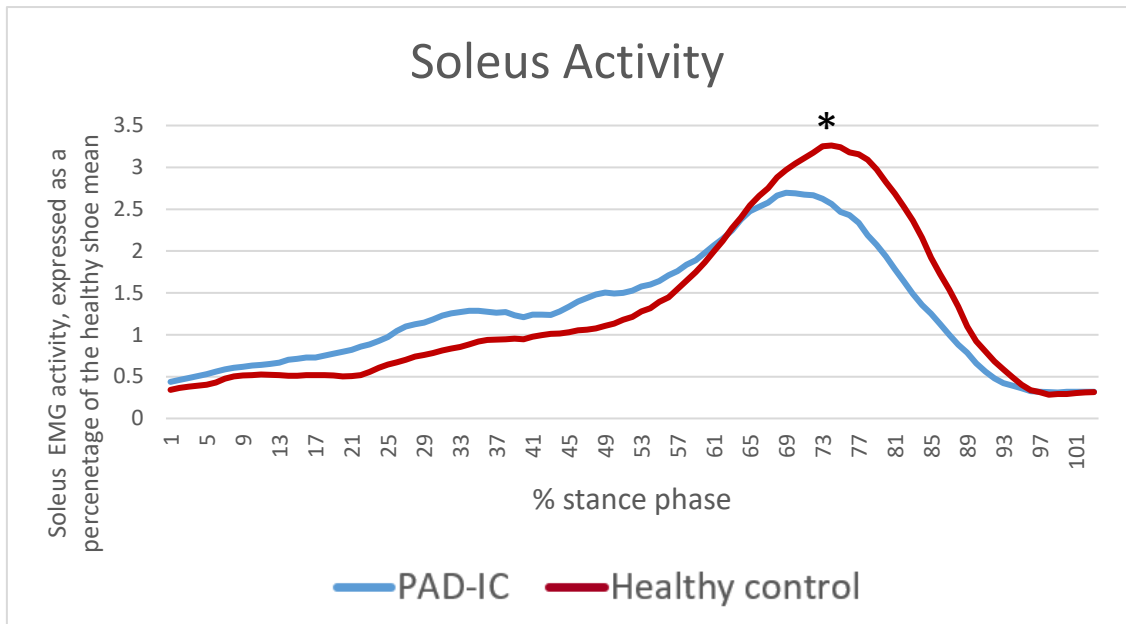


Figure 5.13: Soleus activity in individuals with PAD-IC and healthy controls. Peaks are expressed as a percentage of each group's mean. Significant differences indicated with an asterisk.

Table 5.6: Peak, standard deviation and p value of EMG activity for individuals with PAD-IC and healthy controls. Data normalised to the mean EMG activity for each muscle in each group.

Outcome measure	Peak (PAD-IC)	SD	Peak (Control)	SD	Significance p	power
Tibialis anterior (Mv/stance mean)	2.94	0.74	3.37	0.56	0.112	0.51
Medial Gastrocnemius (Mv/stance mean)	3.98	1.20	4.29	1.07	0.701	0.2
Lateral Gastrocnemius (Mv/stance mean)	3.30	0.86	4.21	0.92	0.016	0.81
Soleus (Mv/stance mean)	2.89	0.62	3.57	0.60	0.010	0.87

Table 5.7: Average un-normalised mean for PAD-IC and healthy controls

Outcome measure	Un-normalised Mean PAD-IC	Un-normalised Mean Control
Tibialis anterior (Mv)	66.21	60.92
Medial Gastrocnemius (Mv)	33.04	42.45
Lateral Gastrocnemius (Mv)	20.90	29.93
Soleus (Mv)	30.49	33.85

Ground Reaction Force

Maximum posterior and maximum anterior ground reaction force (GRF) were significantly reduced in PAD-IC gait compared to control gait ($p = 0.000$, $p = 0.000$). Maximum lateral GRF in early stance ($p = 0.002$) and maximum vertical GRF in early and late stance were significantly reduced in individuals with PAD-IC compared to controls ($p = 0.002$; $p = 0.045$; $p = 0.000$) (table 5.8) (fig 5.14,5.15,5.16).

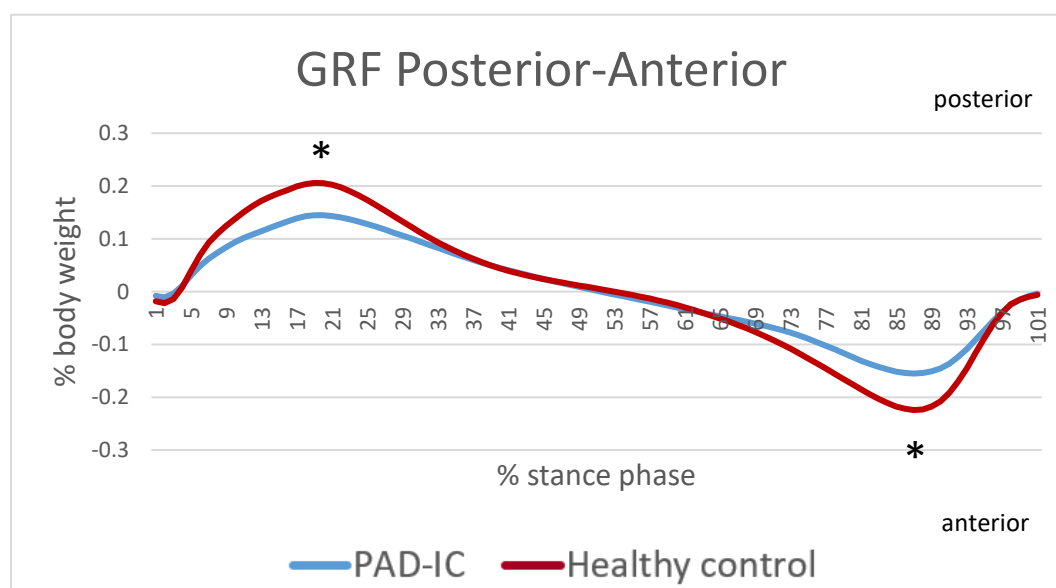


Figure 5.14: Anterior-posterior ground reaction force in individuals with PAD-IC and healthy controls. Peaks are expressed as a percentage of each group's mean.

Significant differences indicated with an asterisk.

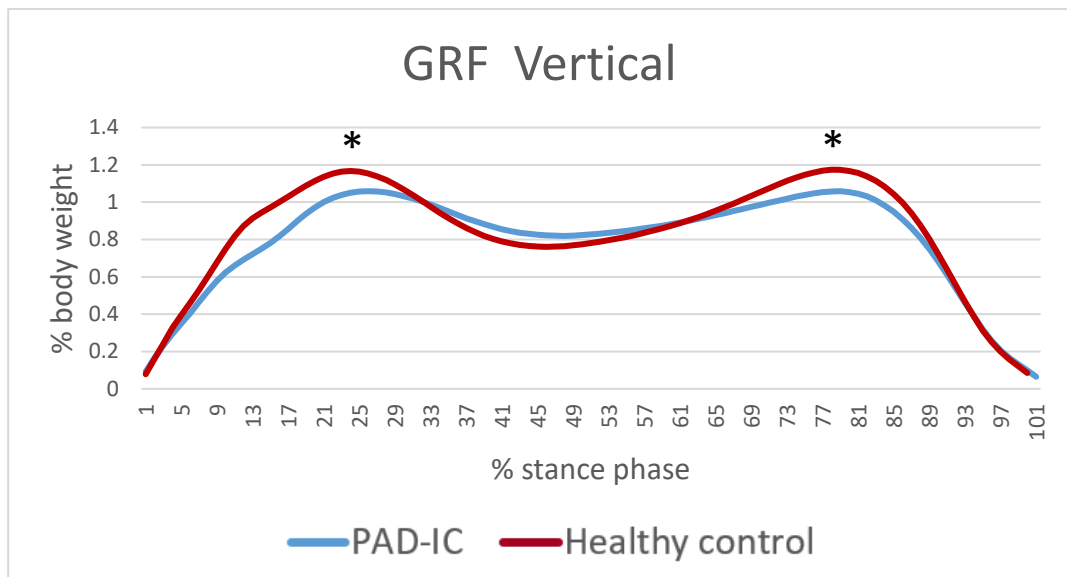


Figure 5.15: Vertical ground reaction force in individuals with PAD-IC and healthy controls. Peaks are expressed as a percentage of each group's mean. Significant differences indicated with an asterisk.

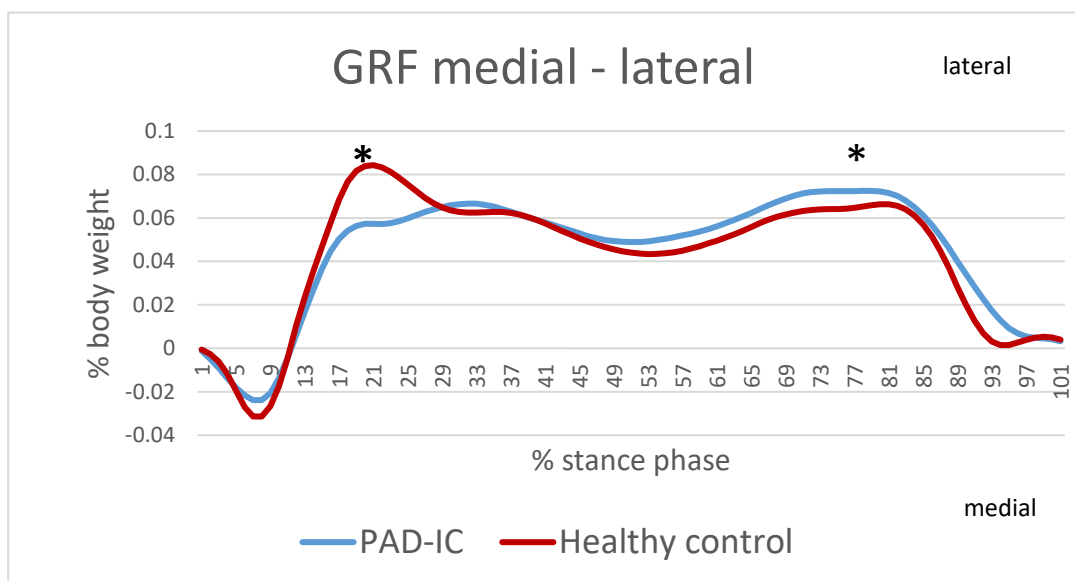


Figure 5.16: Medial-lateral ground reaction force in individuals with PAD-IC and healthy controls. Peaks are expressed as a percentage of each group's mean. Significant differences indicated with an asterisk.

Table 5.8: Mean peak, standard deviation and p value for GRF in individuals with PAD-IC and healthy controls.

Outcome measure	Mean PAD-IC	SD	Mean Control	SD	Significance p	t	df	Effect size
Maximum posterior GRF early stance (N/Kg* g)	0.16	0.03	0.22	0.04	0.000	4.26	35	1.70
Maximum anterior GRF late stance (N/Kg* g)	-0.15	0.04	-0.20	0.03	0.000	-4.9	35	1.41
Maximum lateral GRF early stance (N/Kg* g)	-0.03	0.02	-0.06	0.03	0.002	3.0	35	1.17
Maximum lateral GRF late stance (N/Kg* g)	-0.01	0.01	-0.01	0.01	0.193	0.37	35	0
Maximum vertical GRF early stance (N/Kg* g)	1.08	0.09	1.16	0.15	0.045	-2.11	35	0.65
Minimum vertical GRF mid-stance (N/Kg* g)	0.78	0.04	0.74	0.12	0.170	1.27	14.4	0.45
Maximum vertical GRF late stance (N/Kg* g)	1.06	0.06	1.17	0.1	0.000	-4.11	35	1.33

Vertical GRF remained significantly lower in late stance for individuals with PAD-IC compared to controls ($p = 0.004$) although speed was not found to explain a significant amount of the variance ($p = 0.599$). Both maximum posterior GRF and maximum anterior GRF remained significantly lower for individuals with PAD-IC compared to healthy controls ($p = 0.009$; $p = 0.005$). Speed did not explain a significant amount of the variance ($p = 0.371$; $p = 0.149$). Reduction in lateral GRF in early stance remained significant after adjusting for speed ($p = 0.017$) but speed did not explain a significant amount of the variance ($p = 0.575$).

5.6 Discussion

The current research aims to develop footwear to increase the pain-free walking distance of individuals with PAD-IC. This requires that the gait pattern of these individuals and how it differs from healthy individuals is first understood. Following is a discussion of the current finding as they relate to previous relevant research. In later chapters these findings will be used to evaluate the effects of different interventions on PAD-IC gait and to rate the effectiveness of each intervention.

Ankle

The maximum internal ankle plantarflexion moment was reduced in mid-late stance in individuals with PAD-IC, which is in accordance with previous literature (Koutakis et al., 2010a, Koutakis et al., 2010b). This includes Koutakis et al (2010b) who tested individuals with uni-lateral PAD-IC and Koutakis et al (2010a) who tested individuals with bi-lateral PAD-IC. A decrease in ankle moment in late stance therefore seems to occur irrespective of whether the arterial disease is in one or both limbs. The reduction in internal ankle plantarflexion moment in late stance, along with a reduced step length, point to a reduction in the force production by the calf muscles to propel the limb into swing phase.

The findings for the ankle moment may be caused by the difference in walking speed between individuals with PAD-IC and healthy controls. More specifically, Wurdeman et al (2012) who tested individuals with PAD-IC and age and velocity matched healthy controls, did not identify any difference in ankle moment between the two groups. However, when adjusting for speed in the current study, the reduction in ankle moment remained significant. In this instance, Wurdeman's study can be said to carry more weight, since the effect of speed was controlled for within the study and not simply adjusted for afterwards, as in the current study. However, Wurdeman et al (2012) only reported mean speeds and not step length, which might have remained the same for participants in his study. An increase in step length increases ankle, knee and hip moments throughout stance (Bieryla and

Buffinton, 2015, Schulz et al., 2013). Consequently, the reduced internal ankle plantarflexion moment identified in the current and previous studies, might be a result of the reduction in step length, which was present in the current study even when adjusting for speed. This may denote that the reduced ankle moment is simply the result of a reduced step length and not the ability of the calf muscles to produce force.

However, a smaller step is on its own a sign of reduced function and/or stability at the lower limb (Farinatti and Lopes, 2004, Mak, 2013, Espy et al., 2010). Furthermore studies have proven that muscle degeneration is present in individuals with PAD-IC (McGrae McDermott et al., 2007). This may suggest that a shorter step length is preferred by individuals with PAD-IC because smaller moments will be required in stance, such that the capability of the muscles and task are better matched, and thus walking could be sustained for longer (until pain is reached). This is supported by previous findings of reduced peak isokinetic and concentric torque, produced by the calf muscles of individuals with PAD-IC (Basyches et al., 2009, Câmara et al., 2012). However, the present study is the first to show that this reduction in capacity to produce peak torque is sufficient to cause significant reductions in peak soleus muscle concentric contraction during the push-off phase of gait. This is true despite participants with PAD-IC walking at a self-selected speed which was significantly lower than healthy controls and remained significant even when adjusting for speed.

The significant reduction in ankle power generation and absorption throughout stance (bursts 1,3), supports the reduced ankle moment identified, which points to a reduced force production by the calf muscles. Together, these findings of kinetics, step length and EMG, highlight both the reduced ability of individuals with PAD-IC to use their calf muscles as well as the adoption of a gait pattern that requires less work by the muscles.

It is important to highlight here, that once adjusted for speed, at the ankle besides moment in late stance, only ankle power in late stance (burst 3) was reduced. The finding is very pertinent for two reasons. First, it indicates that the reduction in power in late stance is not caused (to a significant degree) by the reduction in

walking speed. This corroborates the findings of Wurdeman et al (reduction in peak power in late stance) who tested velocity matched controls. It also supports the hypothesis that irrespective of speed, the calf muscles of people with PAD-IC have a reduced ability to generate force in order to propel the stance limb into swing. Secondly, by adjusting for speed, many significant findings cease to be significant. This highlights the importance of taking speed into consideration when studying PAD-IC gait, as many findings of previous studies might have been discounted if speed were considered.

However, this does not make such findings either irrelevant or false as a whole. As mentioned above, the reduction in walking speed can be seen as a conscious, on the part of people with PAD-IC, mechanism to reduce the forces required by the muscles during gait. A reduction in step length offers similar effects. It is therefore likely that the higher the chosen or directed speed of individuals with PAD-IC, the more its effects on different phases of gait will be significant. In the current study participants walked with a lower mean speed than individuals with PAD-IC of similar studies (Koutakis et al., 2010a, Koutakis et al., 2010b, Wurdeman et al., 2012). Consequently, it is possible that fewer significant adaptations were required in the current study (having adjusted for speed) compared to Wurdeman et al. (2012).

Drawing on the findings of the current as well as previous studies, it can be stated with confidence that a decrease in ankle moment and power in mid-late stance, in individuals with PAD-IC, exists as consequence of their condition. Therefore, any footwear intervention designed to increase PAD-IC walking distance should seek to replace the force required by the calf muscles in late stance, to a significant degree, while restoring normal gait. Unfortunately, current kinematic and kinetic data analysis systems are not able to distinguish between internal changes in gait of an individual (i.e due to disease) and changes caused by footwear, directly. This can be done indirectly by critically interpreting the effect of the intervention on the kinematics and kinetics of anatomical joints. Therefore, for a shoe intervention to significantly increase the power output of the shoe-foot system, a kinetic analysis would have to indicate a significant reduction in ankle moment and power when speeds are matched. The reduction in moment and power at the ankle is then, by

hypothesis, possible by being substituted for by the shoe intervention. Consequently, ankle moment and power reduction in late stance, at matched speeds, should be seen as an indicator of the intervention's effectiveness. It should be highlighted that a reduction in ankle moment could also be caused by a pull-off strategy, where the hip flexors compensate for the calf muscles. Therefore, analysis of hip moment and power data would be required to ensure that this was in fact not the case.

Knee & Hip

The reduction in internal flexion moment at the knee at initial contact, the reduction in internal extension moment at the hip in early stance, along with the reduced power absorption at both joints, in early and late stance, indicate that individuals with PAD-IC have reduced eccentric control from the quadriceps while the knee is flexing at heel contact and from heel rise to toe off. Likewise, the reduced power production in mid-stance, indicates a reduced effectiveness of the quadriceps to concentrically contract and support movement of the femur over the tibia. This would indicate a generalized weakness of the quadriceps to control motion.

However, when adjusting for speed, only knee power absorption in early stance, as the knee is flexing whilst being acted upon by a flexion moment, and hip power absorption in early stance (burst 1) were found to be significantly reduced compared to controls. Rather than creating an image of generalised weakness of the thigh muscles, to control the hip and knee and generate force through stance (as was the interpretation in the above paragraph when speed is not taken into account), these findings indicate instead the consequence or mirror effect of reduced ankle moment and power in late stance (burst 3). Specifically, individuals with PAD-IC walk with a smaller step length and use less force to propel the stance limb into swing. The limb travels a smaller distance in swing (reduced step length) and lands, with less force (reduced posterior GRF peak), causing a smaller ground reaction force, which is closer to the knee and hip joints, therefore creating the smaller powers observed at the knee and hip.

Although many findings at the knee and hip become non-significant when adjusting for speed it is still important to consider these findings with respect to similar previous literature because it allows one to compare and contrast the effects of the disease in different types of PAD-IC individuals. In the current study, internal hip extensor moment, created by the concentric contraction of the hamstrings (early to mid-stance) was found to be reduced in individuals with PAD-IC compared to controls. This is in agreement with Chen et al (2008) and Koutakis et al (2010a). However, Koutakis et al (2010b), failed to find the same when they investigated unilateral rather than bilateral patients. This was despite their subject population including some individuals with proximal stenosis sites i.e aortoiliac disease, which should affect the thigh muscles more. This may signify that effects at the level of the hip do not become significant unless both limbs are affected by PAD. This may be due to compensations made by the non-affected limb and the body as a whole. Koutakis et al highlighted that reductions in hip power reflect a reduced ability to control trunk motion. Perhaps claudication in one limb is not sufficient to cause a significant reduction in trunk control. Trunk motion in individuals uni-lateral and bi-lateral PAD-IC has not been directly researched in previous literature. Therefore, future research into adaptations made at the trunk may explain the differences.

Other findings at the hip and knee also differ among previous studies and between previous studies and the present study. The present study is mostly in agreement with most literature (Koutakis et al., 2010a, Wurdeman et al., 2012, Chen et al., 2008) but not all (Koutakis et al., 2010b). Agreement is greatest when bi-lateral or mixed participant groups are examined with a mixture of class II and III Rutherford symptoms. This may highlight the importance of researching unilateral and bi-lateral patient groups separately. Alternatively, it may be the severity of PAD-IC which explains differences in results, since Koutakis (2010b) used participants with class II Rutherford severity (moderate claudication), and the current study and Koutakis et al (2010a) used both class II and III (severe claudication). This would indicate that as the severity of the disease increases, so too do the effects on lower limb kinetics. Future research should focus on identifying the differences in gait between uni-lateral and bi-lateral claudicants, as well as the effects of different level

claudication (femoropoplital/aortoiliac) on gait and severity class of the disease with respect to velocity matched controls.

Ground reaction force

In addition to the findings in joint kinetics, the reduction in peak posterior force in early stance and peak anterior force in late stance, when accounting for speed, indicate that individuals with PAD-IC have less confidence in loading the leg in early stance and reduced confidence and/or muscle strength to propel it into swing in late stance (Richards, 2008). The reduced second vertical peak of the GRF, in late stance, further corroborates the finding. The reduction in anterior-posterior ground reaction forces in early and late stance may, in part, be due to the reduced step length, as previous research has indicated (Martin and Marsh, 1992). However, as stated previously, a reduction in step length is in itself a significant indicator that individuals with PAD-IC are either not confident in loading the foot and pushing off and/or that they choose smaller step lengths because the ground reaction forces associated with longer step lengths produce greater external moments at the lower limbs and hence require greater muscle activity to be countered (Lim et al., 2017). The muscles of individuals with PAD-IC cannot produce these moments as efficiently as healthy counterparts (Câmara et al., 2012) due to degeneration of the muscles and reduced oxygen supply. Indeed, greater demand on the lower limb muscles will cause pain related to IC to present more quickly. Therefore, it is possible that individuals with PAD-IC have gradually adapted to smaller step lengths, which would reduce the peak internal moment requirements at the lower limb, so as to delay the onset of pain as they walk.

EMG

Individuals with PAD-IC walked with 2.9 times of their mean soleus activity while healthy counterparts used an average of 3.6 times their mean activity. No co-contraction between muscles was identified, as seen from the ensemble average plots. The significant reduction in soleus activity may be caused by the aforementioned reduction in step length. A smaller step length could translate into a smaller force demand from the calf muscles during push-off. Therefore,

employing less muscle activity during propulsion may be a further indication of muscle weakness as a consequence of muscle denervation, reduction in lean muscle mass and repeated cycles of ischemia. However, a similar significant reduction was not present in either the medial or lateral gastrocnemius when controlling for speed. The lack of similar findings for the gastrocnemius could be related to the difference in major muscle fibre type between the two muscles. More specifically, the soleus has been found to have a significantly higher percentage of type I or slow twitch muscle fibres (70%) than the gastrocnemius (50%) (Edgerton et al., 1975). These muscle fibres are more resistant to fatigue but produce less strong contractions than fast twitch (type II) muscle fibres. Furthermore, it has been found that, in individuals with PAD-IC, the percentage of slow twitch (type I) muscle fibres is increased in their calf muscles (Regensteiner et al., 1993, England et al., 1992). This would mean a further increase in the slow twitch muscle fibres in the soleus, which would, in turn, reduce its peak force production. Overall, EMG findings are in agreement with kinetic findings. The reduction in ankle moment and power indicate an overall reduction in muscle effort. The EMG analysis indicated that the muscle most likely responsible for the reduction in internal moment is the soleus muscle, possibly due to fibre changes in the muscle (England et al., 1992, Regensteiner et al., 1993). However, this does not necessarily mean that other muscles may not contribute to the reduction in moment too.

The reason for the lack of observed difference could have been the lack of statistical power associated with findings for the tibialis anterior and medial gastrocnemius. This is most likely associated with the low sample size of 13 participants.

The EMG findings compliment temporal-spatial and kinetic findings and together indicate that PAD-IC gait is more restricted compared to healthy age matched controls. The resulting reduced step length and speed, coupled with the associated reduction in moments and powers at the lower limb joints indicate a gait that has been adjusted to either delay the onset of pain and/or function at a level the lower limb musculature is capable of. Furthermore, having adjusted for speed, the reduction in ankle moment and power in late stance along with the reduction in

peak soleus activity, further support a functional weakening of the calf muscles as a consequence of PAD-IC.

An important conclusion from this study and the literature is that PAD-IC is a multilevel, multi-stage disease which may lead to different gait related effects according to the level and severity of the disease and the physical state of the patient. Changes at the level of the ankle are almost unanimous across studies and patient groups and are most characteristic of the condition. This is not surprising given that the calf muscles act mainly around the ankle. Proximally, there is some disagreement between studies, possibly due to differences in the disease level (distal/proximal) and severity between studies, but also, due to only two studies (the current being one) considering walking speed as a factor.

5.7 Conclusion

The findings of the current study in conjunction with previous findings allow us to create the following list (fig 5.16) of effects of PAD-IC on gait:

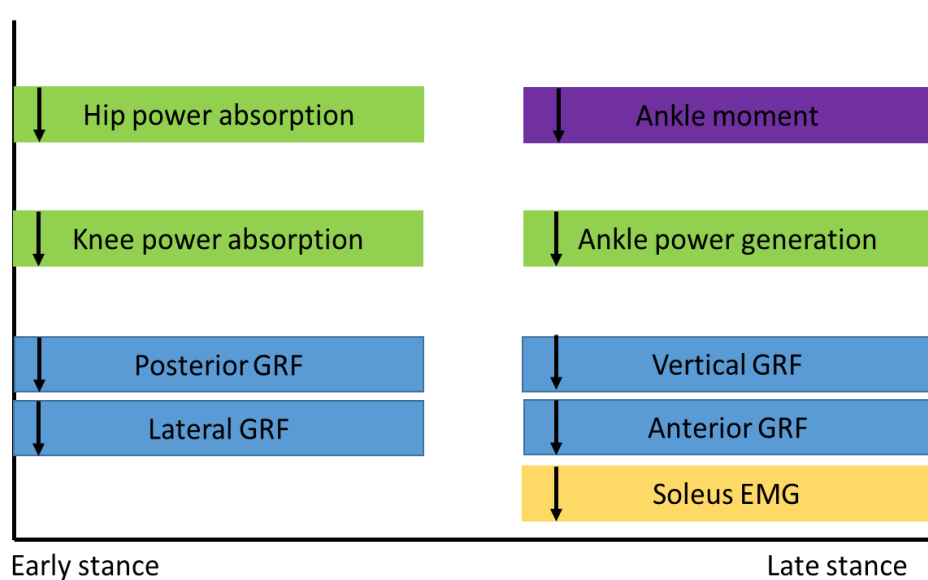


Figure 5.17: Effects of PAD-IC on gait, having adjusted for speed.

- Reduced internal ankle plantarflexion moment in late stance
- Reduced ankle power generation in late stance
- Reduced internal knee flexion moment at initial contact
- Reduced knee power absorption in early stance
- Reduced hip power absorption in early stance
- Reduced peak posterior ground reaction force in early stance
- Reduced peak anterior ground reaction force in late stance
- Reduced peak vertical ground reaction force in late stance
- Reduced peak lateral ground reaction force in early stance
- Reduced peak EMG activity of soleus muscle

All the findings indicate a reduced ability of the lower limb muscles, primarily those of the calf, to produce the forces required to efficiently move the stance limb from

heel strike to toe off. The reduced blood supply to these muscles in conjunction with the muscle denervation and decrease in type II muscle fibres, all identified in other studies (Regensteiner et al., 1993, England et al., 1992), help explain these results. Both a denervation of the nervous connection between the spinal cord and these muscles and the increase in type II muscle fibers, which are more resistant to fatigue but are capable of lower contractions, will inevitably cause the slower gait identified (McGrath et al., 2012) (Koutakis et al., 2010a, Chen et al., 2008, Celis et al., 2009).

Within the context of this thesis, the evidence for limited calf muscle function in cases of PAD-IC suggests that footwear designed to reduce the external ankle dorsiflexion moment in late stance (so that internal moment can be reduced), and thus reduce the ankle power required in late stance, would significantly reduce the work load of the calf muscles. This in turn should increase pain free walking distance but also allow individuals with PAD-IC to complete that distance in a more energy efficient manner. Changes in the ankle moments and power due to the footwear should be supported by with a reduction in calf muscle EMG activity during stance, primarily at the gastrocnemius and soleus (as these contract concentrically in late stance to push the foot off the ground) as well as maintenance or reduction in the knee and hip moments primarily in mid and late stance, as well as. Chapter 6 will address the design and effectiveness of such potential footwear aids.

**Chapter 6 Effects of rocker soled shoes and an ankle – foot
orthotic on gait of PAD-IC**

6.1 Introduction

To date, studies offer an incomplete description of the effect of shoes on PAD-IC gait and calf muscle activity. Where footwear has been investigated the footwear designs have not been fully described, controlled, and effects have not been fully described with an appropriate range of data. Many studies have not involved any cases of PAD-IC, whereas it is known PAD gait differs from normal healthy gait. Some ankle-foot orthotic (AFO) designs also offer the opportunity to alter calf muscle activity but have not previously been investigated in cases of intermittent claudication. Finally, specific shoe and orthotic features (such as rocker sole angle, positioning and pitch of the shoe) have not yet been explicitly linked to changes in the forces and moments at the lower limb during walking and thus the resulting changes in calf muscle activity. Optimising their design has therefore not been possible thus far. In the context of these gaps in the literature, the work in this chapter investigates the effects of three rocker soled shoes and these shoes combined with a rigid AFO on the gait and calf muscle activity of individuals with PAD-IC. The findings are discussed in light of the findings in chapter 2 (literature) and chapter 5 and the most effective intervention is identified as a precursor to the work in Chapter 7.

6.2 Aims and Objectives

Aim:

To determine the effect of three rocker soled shoes and rocker shoe plus AFO combinations on the gait kinematics, kinetics and EMG related muscle activity in people with PAD-IC.

Objectives:

- Calculate and compare lower limb angles, moments, powers and EMG activity of the calf for footwear and orthotics with footwear interventions

- Create a decision algorithm to objectively judge the footwear and footwear plus orthotic interventions against pre-defined criteria
- Understand the relationship between the footwear design features their effects on gait.

6.3 Methodology

Kinematic, kinetic and EMG data were collected for 18 PAD-IC participants, 17 of whom were the same as those who took part in the study outlined in chapter 5 (table 6.1). The remaining participant chose not to complete the full data collection session and was therefore excluded from the study due to lack of data. The two studies took place on the same day, during the same testing session. Participants were aware of this in advance, through the invite letter and information sheet, and the consent form. One participant whose data was used in chapter 5 chose not to complete all conditions for the study in chapter 6. Consequently, an additional participant was recruited for the current study. The protocol of the study remained identical to that described in chapter 5.

Table 6.1: Participant demographics and temporal-spatial parameters.

	PAD-IC
Male	12
Female	6
Mean Age	68.1(SD = 8.1)
Mean Height	1.70 (SD = 0.08)
Mean Weight	75.3 (SD = 12.4)
Mean Walking Speed	0.98 (SD = 0.25)
Step length	0.62m (SD = 0.07)
Diabetes	2
Unilateral claudication	6
Bi-lateral claudication	12

Data was collected as participants walked in three rocker soled shoes and these three shoes combined with an ankle-foot orthotic (AFO). All shoes were available in

sizes 37-41 for women and 40-45 for men. Therefore, a shoe size smaller or larger than the ones available consisted an exclusion criterion.

Before data collection, each participant walked across the laboratory five times, while wearing the first shoe plus AFO condition, and their mean self-selected speed was calculated. Due to the nature of the AFO, the gait of an individual whilst wearing it may be reduced. Therefore, participants performed the initial five walks to determine speed whilst wearing the AFO. Had participants' mean speed been calculated without wearing the AFO there was a small possibility that this speed would not have been met by them during the shoe plus AFO conditions. Walking speed was then controlled among shoe and orthotic conditions by ensuring that only trials with $\pm 10\%$ of the mean walking speed were used. Where possible trials within $\pm 5\%$ of mean speed were used.

For the purposes of data collection participants completed five successful walks in each condition following a pre-determined random order, with the stipulation that the first condition had to include walking with the AFO (www.randomizer.org). As explained above, this was done based on the assumption that walking with the AFO might reduce the self-selected speed of participants compared to walking only with shoes. Therefore, if the mean speed of the participant was computed when wearing only a shoe, then that speed may have been too difficult for the participant to reach in the shoe plus AFO conditions. A walk was considered successful when EMG was collected successfully, all markers were visible, speed remained within $\pm 10\%$ of the mean and the most affected limb of the participant made contact with the force plate.

Participants also answered a non-validated questionnaire on perceived stability and perceived level of work of the lower limb muscles after walking in each shoe (during their rest period). A custom questionnaire was developed because no validated questionnaire was found in the literature. Wording of the questions was informed by discussions with a group of 15 individuals with PAD-IC in an exercise clinic. Originally, the aim of the questionnaire was to inform the researcher of participants' first impressions of each shoe and to ascertain whether any of the designs caused any substantial pain, imbalance or reason for concern. Since the sole

purpose of the questionnaire was to provide some initial insight of participant view, it was not originally meant to be presented in this thesis. However, because the questions pertaining to balance and to the willingness of participants to wear the interventions are very pertinent, these will be presented in the results sections. The questionnaire itself can be found in the appendix section.

6.3.1 Footwear and orthotic Interventions

Participants with PAD-IC completed walking trials in a control shoe, three rocker soled shoes and the same three rocker soled shoes with the addition of a rigid pre-fabricated AFO. The rocker shoes used were the three-curve rocker soled shoe used by Huthins (Hutchins, 2007) (H3C), the corrected three-curve rocker soled shoe (C3C), the two-curve rocker soled shoe used by Hutchins (2C), a control shoe (C), the corrected three-curve rocker soled shoe plus rigid AFO (C3C plus AFO), the Hutchins three curve rocker soled shoe plus rigid AFO (H3C plus AFO) and the two-curve rocker soled shoe plus rigid AFO (2C plus AFO).

Table 6.2: Table of conditions assessed and abbreviations used.

Rocker soled shoe name	Abbreviation
Two curve rocker soled shoe	2C
Hutchins three curve rocker soled shoe	H3C
Corrected three curve rocker soled shoe	C3C
Two curve rocker soled shoe plus ankle foot orthotic	2C plus AFO
Hutchins three curve rocker soled shoe plus ankle foot orthotic	H3C plus AFO
Corrected three curve rocker soled shoe plus ankle foot orthotic	C3C plus AFO

As an outcome of the literature review, the three and two curve rocker soled shoes designed by Hutchins (Hutchins, 2007) were identified as representing current state of the art for footwear in cases of PAD-IC. Hutchins (2007) showed that both shoes caused changes in gait kinematics, kinetics and muscle activations which would be beneficial to individuals with PAD-IC. The three-curve rocker was also tested in a pilot study on individuals with PAD-IC to determine maximum walking distances and pain levels which were found to increase and decrease accordingly (Hutchins et al., 2012). Furthermore, the sole design geometry is specified in detail and thus relatively easy to execute (complimented by personal communication with the author).

However, as discussed in the literature review, the shoe design, which relies on curves based on distances of the lower limb joints to the ground, did not account for the thickness of the shoe sole. This important anomaly was addressed in this study by designing a three curve rocker soled shoe with the appropriate offset applied and thereby testing the three curve theory for the first time.

The effects of this modified three curve shoe on gait were compared to those of the *Hutchins 3 curve and 2 curve rockers* (defined as per Hutchins (Hutchins, 2007), i.e. without accounting for sole depth). However, the offset described above was only applied to the 3 curve shoe not the 2C. The reason for this is that the two curve rocker soled shoe was added to the study to assess how the different number of sole curves (2 and 3) would affect PAD-IC gait. This was done to establish a correlation and/or an understanding of the connection between shoe design and biomechanical effect. However, as a shoe the 2C was found less effective than the H3C at reducing moments and powers in Hutchins' study. For this reason the corrective offset that was applied to the H3C, yielding the C3C, was not applied to the 2C.

6.3.2 Shoe design

A standard last and upper were selected for all shoes used in the study so that the shoe soles were the independent variable. Each of the soles were made separately

and according to the design specification which will be outlined in the sections below.

In order to design the sole of the three and two curve rocker soled shoes according to the Hutchins et al protocol (and modifications of it using an offset), the following design parameters were needed: centre and radius of each curve, angle of apex, horizontal distance from heel to lateral malleolus, position of 62.5% of shoe length, height of lateral malleolus from floor, height of knee from floor, height of hip from floor, shoe size. These are depicted in figures 6.1 and 6.2 of the C3C design and table 6.3 which outlines the design parameters of the C2, H3C and C3C shoes below:

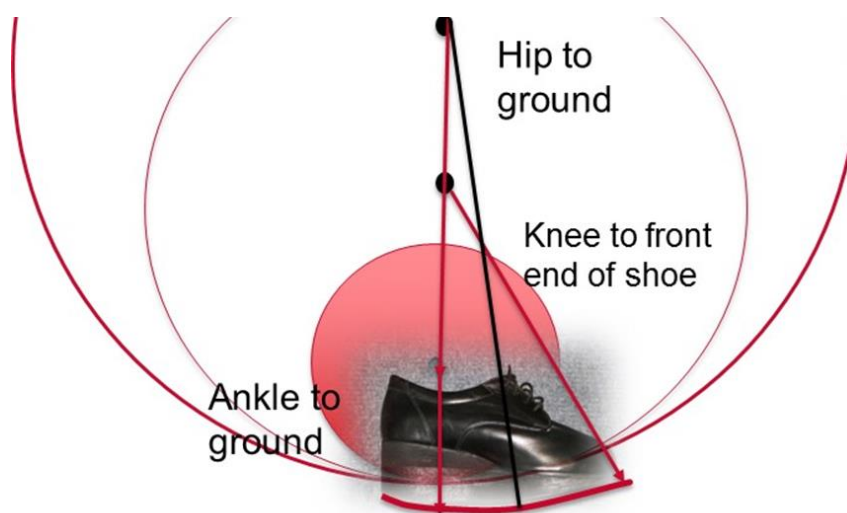


Figure 6.1: Circles used to design the C3C, centred at the ankle, hip and knee accordingly.

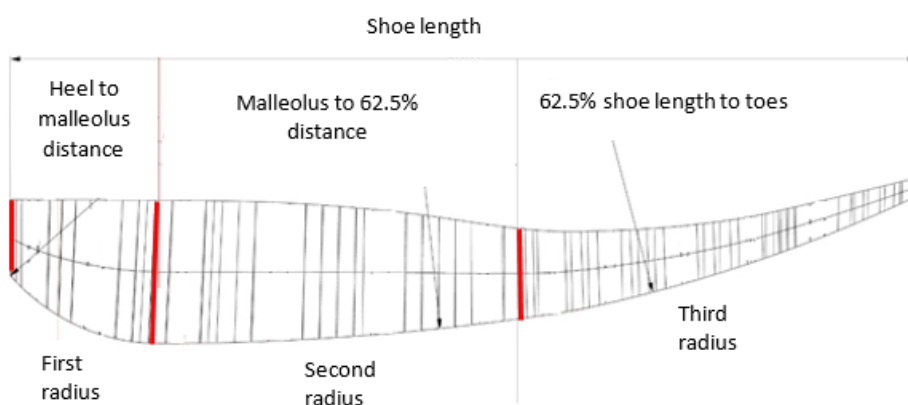





Figure 6.2: Design elements of the C3C shoe.

Table 6.3: Design parameters of the H3C, C3C and 2C shoes.

Shoe types	Design parameters	
H3C	<p>1st curve apex at level with lateral malleolus (centre ankle)</p> <p>2nd curve centred at hip (greater trochanter)</p> <p>3rd curve apex at 62.5% of shoe length (centred at knee)</p>	
C3C	<p>1st curve apex at level with lateral malleolus (centred at ankle)</p> <p>2nd curve centred at hip (greater trochanter)</p> <p>3rd curve apex at 62.5% of shoe length (centred at knee)</p> <p>1st curve offset 4.5 cm , 2nd curve offset 3.5, 3rd curve offset 2.5 cm</p> <p>offsets equivalent to thickness of the shoe sole</p>	
2C	<p>1st curve apex at level with lateral malleolus (centre at ankle)</p> <p>2nd curve from end of first curve to end of shoe (centre at hip)</p>	

6.3.3 Standardisation of shoe design

The shoe soles were designed using CAD software and manufactured using a precision milling machine to ensure accuracy in curve profiles. In order for the shoes to be standardised (i.e. not tailored to each participant, standardised for each shoe size and designed using a single protocol across shoe sizes), bearing in mind that the curves of the sole are based on distances from the lower limb joints, it was necessary that shoe size and the vertical distances from ankle to ground, knee to ground and hip to ground were linked mathematically. This was achieved in 3 steps.

For the first step a link between foot length and body height was identified. This was done because distances between anatomical landmarks (i.e. distance from the ankle to the ground) are related to body height. Therefore, for an association with foot length to be made, foot length and body height should also be bound by a mathematical relationship. Several studies have researched this relationship and offered equations to estimate one based on the other (Krishan and Kanchan, 2013, Pawar and Pawar, 2012). However, Grivas et al. is the only European study and as such offers greater relevance to the current population in comparison to Asian studies (Grivas et al., 2008). Furthermore, Grivas et al (2008) tested a much larger sample size (5039 individuals) compared to similar studies (200 individuals) (Pawar and Pawar, 2012) and results from the equations presented have a smaller standard deviation in comparison to other studies. Grivas et al (2008) assessed the relationship between foot length and height in adolescent children and offer univariate and multivariate equations for each gender. The multivariate equations consider age as a significant factor. However, since age has a much greater correlation to height in adolescent children than in adults, the univariate equation, with a reliability coefficient of ($r = 0.75$), was chosen to determine respective change in body height with increase in foot length (Grivas et al., 2008).

$$\text{Body Height (cm)} = 17.369 + 5.879 \times (\text{right foot length (cm)})$$

Once the mathematical relationship was identified, and given the fact that the shoes were to be pre-fabricated and the same for all participants (i.e. not bespoke), a compromise had to be made between accuracy and ease of manufacture. Because

the shoes would not be tailored to each participants and therefore foot length of each individual would not be measured as an input to the shoe design process, its relation to the shoe size had to be identified indirectly. Several resources provide this relation between foot length and shoe size and for the purposes of the current study the following online source was used (<https://www.clarks.co.uk/fitguide>). In this way shoe size was approximately mathematically linked to body height.

For the third step, the mathematical relationship between body height and the distance of the ankle to ground, knee to the ground and hip to the ground needed to be identified. This is because these distances represent the radii of the three arcs used to design the sole of the shoe. Because these distances differ from person to person and because the shoes would not be tailored to each individual, a method of standardising the distances according to shoe size was needed. A mathematical relationship between shoe size and body height was identified in the previous two steps. Therefore, the ankle, knee and hip to ground distances needed to be linked to height so that they could in turn be linked to shoe size.

An online scaling calculator (designed by Penn University) was used to extract lower ankle knee and hip height for each corresponding shoe size height (http://openlab.psu.edu/tools/proportionality_constants.htm). This uses ratios according to Drillis and Contini (1966) and the Army Anthropometry Survey (ANSUR) database to calculate segment height based on the overall height of an individual. It is understood that segment ratios may not always be representative. However they offer some reproducibility and consistency to the method. The ratios used for the hip to ground and knee to ground distances have acceptable correlation coefficients of 0.75 and 0.76 accordingly, but ankle to ground distance correlation is very poor (0.21). However even this admittedly very poor correlation offers a slightly better option than using a fixed ankle height for all shoe sizes, and hence for all heights.

Finally, the horizontal distance of the heel to the ankle was measured as the distance between the most posterior point of the calcaneus and the right lateral malleolus using a database of 50 individuals (Chapman, 2014) divided into groups according to shoe size: 37-39 40-42, 43-44. The average distance for each group

was calculated and used in the design of the shoes. Again, it is understood that this is by no means a method devoid of error. However, at present there is no alternative method of accurately identifying lower limb joint heights according to shoe size, nor has such precision and correlation been sought before between shoe soles and the human anatomy. The only other method of ensuring the highest degree of accuracy in the sole curves would be to tailor each assembly of shoes to each participant (i.e. fully customised shoes), and for reasons of cost and practicality these were not deemed appropriate in the long term (and thus not during the study).

6.3.4 AFO design

A rigid AFO set at 90 degrees to the floor was used (fig 6.3). Due to the high price associated with custom AFOs, which are not always financially accessible to patients, pre-fabricated AFOs were produced at the University in three sizes: small, medium and large and the fit was adjusted with extra padding.



Figure 6.3: Example of ankle foot orthotic (AFO) used in the study.

6.3.5 Data processing

All data was processed in the exact same manner and sequence outlined in chapter 4. After being analysed in Matlab (4.2.3.j)

EMG processing was completed in a slightly different manner to chapters 4 and 5 so that the data could be easily visualised and understood by the reader. More specifically, EMG signals were exported into excel spreadsheets, where the average peak of the control condition (the mean of the peaks across five trials), during stance phase, for each participant, was calculated for each of the four muscles and all trials for all conditions were normalised to these average peak values. Therefore, the average peak of each muscle in the intervention conditions was expressed as a decimal of the average peak of that muscle's activity for that participant in the control shoe. This allowed the representation of muscles activity on a scale of 0 to 1, with 1 representing the average peak muscle activity in the control shoe for that particular muscle.

6.3.6 Statistical analysis

Within factors repeated measures ANOVAs were performed to compare lower limb maximum and minimum joint angles, moments, powers and EMG activity of the calf muscles for the four shoe conditions. This was followed by two-way repeated measures ANOVAs between all the interventions. This allowed for the determination of any significant additional effects of the AFO to the existing effects of each shoes, while also providing information about the relative effectiveness of each intervention compared to the rest. Specifically, in the two-way ANOVA, all shoe interventions were considered as a single group, and their mean effect was compared by the software to the mean effect of adding an AFO. Paired t-tests were performed where necessary to determine which shoes the AFO significantly affected ($\alpha = 0.05$). For these the p value was adjusted according to the Bonferroni correction. For EMG results that were not normally distributed, the Friedman test was used, followed by pair-wise comparisons using the Wilcoxon test and Holm-Bonferroni correction. The Holm-Bonferroni is less strict than the Bonferroni correction and was deemed as more appropriate for the analysis of EMG data to reduce the possibility of type I error.

6.3.7 Interpretation of data – Decision tree

While statistical analysis allows for the identification of significant changes caused by the shoes on kinematics, kinetics and EMG activity, it does not provide a means of determining which intervention causes the most pertinent changes in gait. This is because not all kinematic, kinetic etc. data is equally relevant to reducing calf muscle activity and pain free walking distance in people with PAD-IC. Therefore, in order for the data to answer the research question and the clinical need it represents, a 2-step process of data interpretation was designed. The first step consisted of calculating the magnitude of change in each gait parameter compared to the control shoe. The second step involved using a decision tree to prioritise interpretation of the statistical differences that were identified.

The objective of the decision tree was to prioritise the study outcome measures according to their relevance and importance to increasing pain-free walking distance. Therefore, using the tree would allow for rating of the three rocker soled shoe interventions in order of likely effectiveness. For the tree to achieve its purpose it had to take into account both the importance of the outcome measure (interpreted as the significance in the link between the outcome measure and increasing walking distance) and the magnitude of change that each intervention caused. For example, two interventions might reduce ankle moment in late stance, but one may reduce it twice as much as the other, and thus potentially be twice as effective.

The ranking of the interventions was accomplished as follows:

STEP 1: CALCULATING THE RELATIVE MAGNITUDE OF THE DIFFERENCES BETWEEN THE CONDITIONS:

- For each participant the maxima and minima of each outcome measure **for the control** shoe were identified and the standard deviation (SD) of these points were calculated.

- The maxima and minima of each outcome measure for the rocker soled shoes were calculated.
- The differences between the control shoe maxima and minima and those of each rocker soled shoe condition were calculated.
- These differences were then expressed as a percentage of the number of standard deviations from the mean of the control shoe and assigned to a value X.
- X was then multiplied by a corresponding weighting factor and then assigned to a value L for each level of the decision tree (figures 6.4-6.6). The weighting of each outcome variable was set according to its relevance to and importance in increasing pain-free walking distance. The reasoning and justification of this weighting system can be found in the table and section below.

6.3.8. Weighting factors and justification

The weighting of the outcome measures is designed on a scale of one to five from least to most important (table 6.4). The scale reflects 5 levels of pertinence that an outcome measure could have to indicate that a specific shoe is effective at reducing the force required by the muscles. In essence, the outcome measures were ranked against each other on the likely strength of their relationship to muscle force. This was not based on prior research but a novel methodological tool developed for this thesis. It allowed for the decisions on the relative effectiveness of each shoe to be made by taking all findings into account but differentiating between the relative importance of their various effects. The relative weighting of outcome measures and defence of these is presented below.

Table 6.4: Table of weighing factors to important outcome measures. 5 = most important outcome measure, 1 least important outcome measure.

Outcome measure	Weighing factor
Peak ankle moment and power – Late stance	5
Medial & Lateral gastrocnemius and soleus peak activity and overall activity	4
Ankle moment & power – Early stance	3
Knee extension moment and power generation – Late stance	3
Knee flexion moment and power absorption –Early stance	2
Tibialis anterior peak and overall activity	2
Hip moments and powers in early and late stance	1

Peak ankle moment and power in late stance have the highest weighing of five.

This is because these variables occur in late stance and thus correspond to the period when the greatest demand is placed on the gastrocnemius and soleus muscles. Whilst the aim of the footwear is to reduce the activity of these muscles and EMG can reflect this, EMG is not a direct measure of force produced by muscles nor physiological demand for blood. It is also less reliable data compared to kinetic data, as it is more variable. Therefore, a reduction in late stance ankle moment and power were expected to be the strongest and most reliable sign that the demand on these muscles was reduced by a specific shoe. If a shoe condition did not significantly reduce these parameters it would be considered ineffective and discarded.

Medial, and lateral gastrocnemius and soleus activity have a weighing of four. It is these muscles that most often claudicate and it is their activity that the footwear aim to reduce. However, as mentioned above, since EMG is less accurate than

kinetics they were appointed a weighing of four, one point less than late stance ankle moment and power.

Ankle moment and power in early stance has a weighing of three. These should ideally be reduced, as this signifies a reduction in the demand of the tibialis anterior, which can also claudicate. However, parameters related to early stance are considered relatively less significant factors associated with IC pain. This is due to the fact that in early stance the tibialis anterior is only eccentrically controlling the lowering of the foot to the ground; which requires less energy than a concentric contraction. On the contrary, in late stance, the gastrocnemius and soleus are required to concentrically contract to lift the heel, which places a much greater demand on the calf muscles.

EMG of tibialis anterior has a weighing of two. As described in the previous section EMG reflects muscle activity but less reliably than moment and power. It is therefore an imperative outcome measure but has a weighing one point less than the respective aforementioned kinetic variables.

Knee extension moment and power generation in late stance has a weighing of three. These should ideally be reduced or remain unchanged by the footwear. However, it may be the case that the footwear increases the moments and powers at the knee. This could lead to excess strain on the tissues and ligaments around the joint. Furthermore, the potential increase in demand on the thigh muscles may lead to a further reduction in the blood supply to the calf, which may cause the calf muscles to claudicate sooner. It is therefore important that the effect of the footwear at the knee is studied and taken into consideration. Due to the potential for long-term damage the variables at the knee are given the same weighing (three) as those at the ankle in early stance.

Knee flexion moment and knee power absorption in early stance has a weighing of two. Knee flexion is less likely to cause tissue damage than knee extension and the forces required by the lower limb muscles are smaller because they are associated with controlling motion, not counteracting the ground reaction force.

Consequently, the weighing given is one less than knee extension moment and knee power production.

Hip moments and powers in early and late stance have a weighing of one. This is because the hip is the most proximal joint and least likely to directly affect calf muscle action and demand for blood.

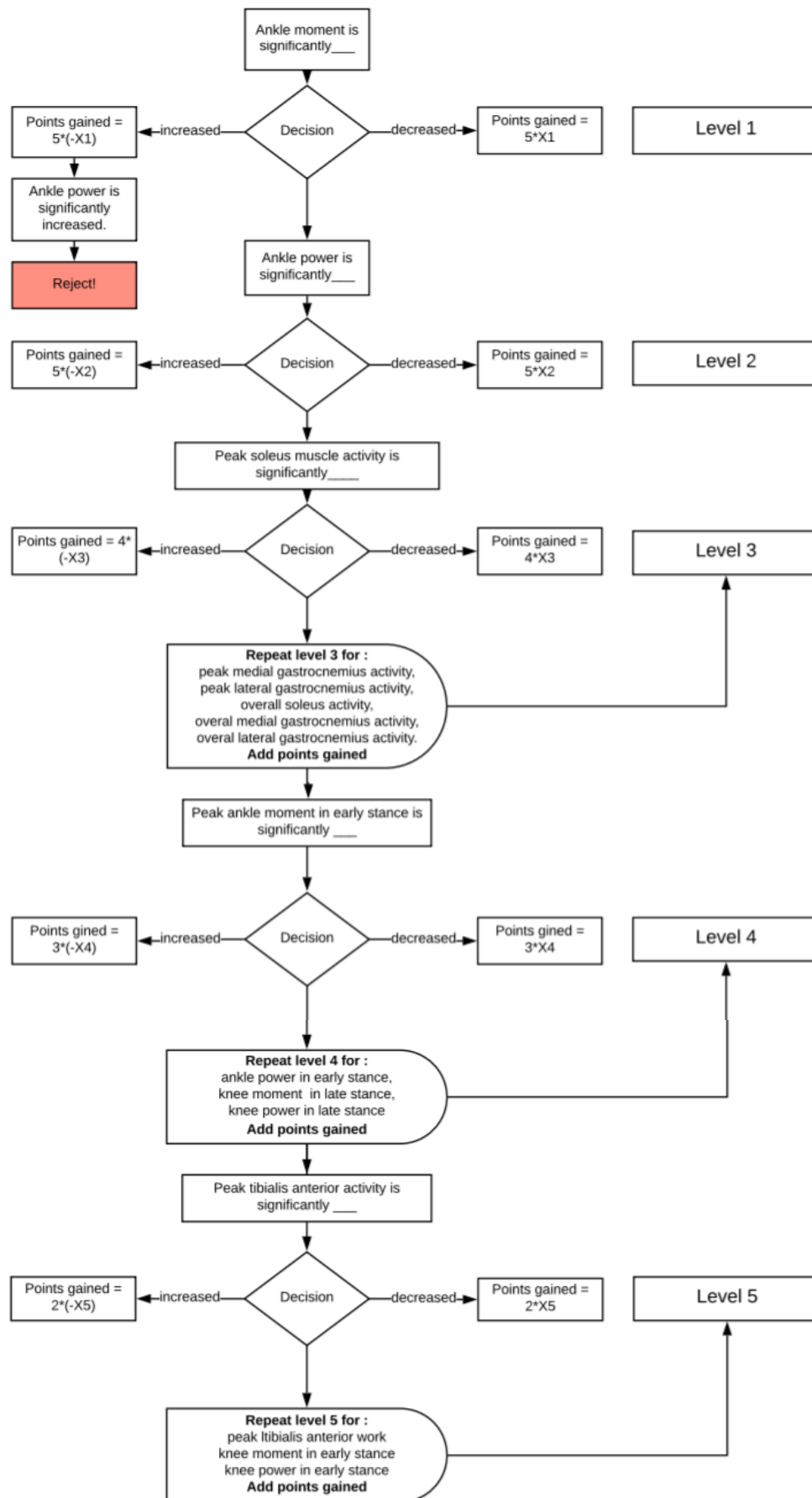
STEP 2 DECISION TREE:

- For each outcome measure considered in the decision tree the process in Step 1 was repeated. At each level in the decision tree, each rocker shoe received a score (P) on its ability to positively (according to the objectives of the study) or negatively alter each outcome variable.

If a shoe did not statistically significantly alter the **main** outcome measures (moment and power at the ankle in late stance) the condition was rejected.

- If a shoe condition did not statistically significantly alter other outcome measures, it received a null score at that particular level of the tree.
- If a shoe condition negatively altered an outcome measure they received a negative score.
- After progressing through all levels of the decision tree each shoe received a total score, which was the sum of scores from all levels of the decision tree.
- The shoe with the highest total score would be the most effective option for increasing IC pain-free walking distance.

The following figure presents the decision tree (fig 6.4). In total it comprises of six levels. Each level and the scoring procedure are presented



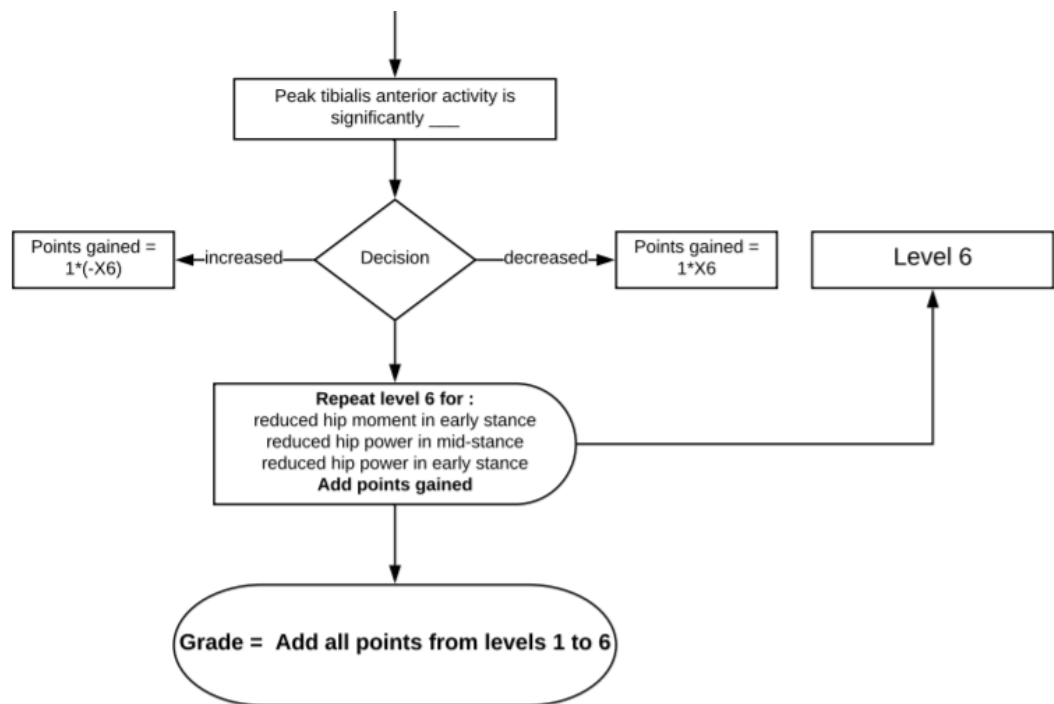


Figure 6.4: Decision tree depicting the 6 levels and commands for making decisions at each level

Working example: First level of the tree

1. Does the shoe condition significantly reduce max ankle moment in late stance?

Ankle Moment	Max	StDev	X1	5*X1
Control	1.42	0.55		
2C	1.45	N/A	-0.06	-0.30
H3C	1.28	N/A	0.25	1.26
C3C	1.23	N/A	0.34	1.71

$$X1 = (\text{Control_max} - \text{2C rocker max}) / \text{StDev_control}$$

= $1.42 - 1.45 / 0.55 = -0.30$, where X1 is the difference of each rocker shoe peak (here of 2C shoe) from the control peak, per standard deviations away from the control peak.

The value X, derived for each condition is then multiplied by a weighting factor according to the variable's importance and relationship to the clinical and

biomechanical objectives of the footwear, and assigned to a value L for that level of the tree

i.e Ankle moment – late stance weighting factor = 5

Points from level 1:

2C: $5 * (-X) = 5 * (-0.06) = -0.30$ (IF ANKLE POWER ALSO NEGATIVE SHOE WILL BE REJECTED)

H3C: $5 * X1 = 5 * 0.25 = \mathbf{1.26}$

C3C: $5 * X1 = 5 * 0.34 = \mathbf{1.71}$

The process above is then repeated for each level in the decisions tree.

6.4 Results

Ankle

None of the rocker soled shoes caused changes in ankle angle throughout stance (table 6.6). The internal ankle plantarflexion moment in late stance was significantly reduced by the H3C and C3C conditions compared to the control shoe, but there was no significant difference between the C3C and H3C. Internal ankle plantarflexion moment in early stance was not significantly affected by any of the shoes (table 6.6) (fig 6.5).

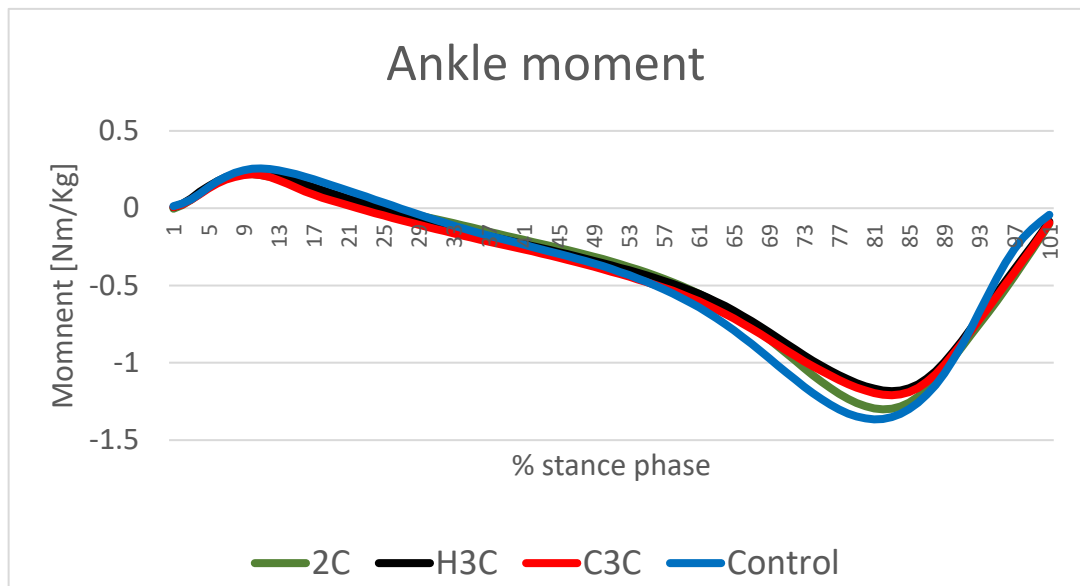


Figure 6.5: Stance phase ankle moment when walking with the 2C, H3C, C3C and Control shoes.

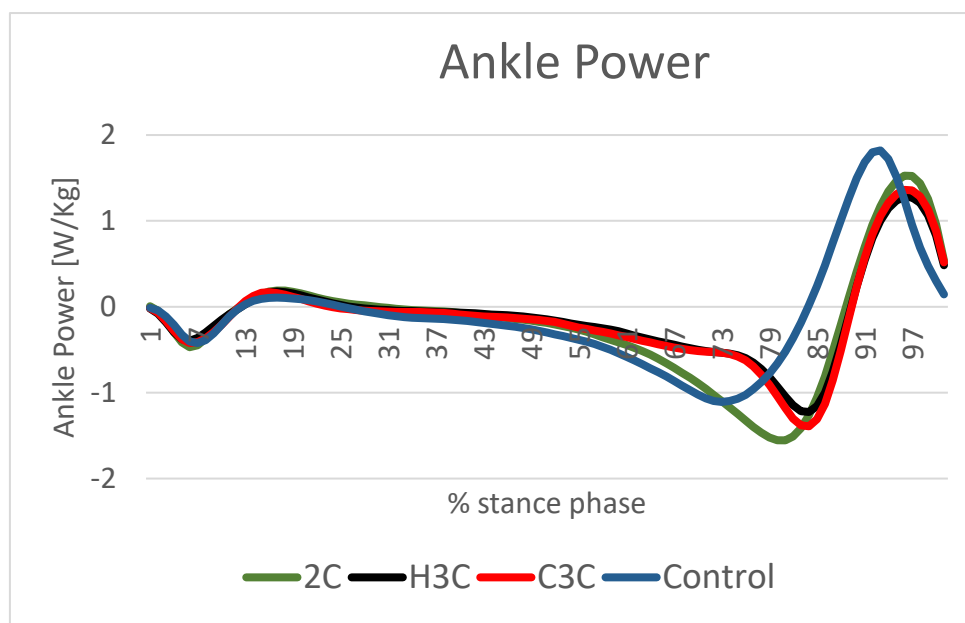


Figure 6.6: Stance phase ankle power when walking with the 2C, H3C, C3C and Control shoes.

Ankle power in late stance was significantly reduced by the H3C and C3C conditions, with no significant difference being found between the two. Ankle power in mid-stance was significantly increased by the 2C rocker soled shoe. Neither the H3C nor the C3C rockers had a significant effect. Ankle power in early stance remained unchanged compared to control for all shoe conditions (table 6.6) (fig 6.6).

The addition of an AFO to the shoes significantly decreased peak plantarflexion in early stance and peak dorsiflexion in late stance, compared to the respective shoe-only conditions (tables 6.7-6.8).

The AFO also significantly increased internal ankle dorsiflexion moment in early stance for the C3C and offered no significant benefit compared to the shoe conditions for plantarflexion moment in late stance, compared to the shoe-only conditions (tables 6.7-6.8).

Adding the AFO, to all three rocker soled shoes, significantly reduced ankle power in early stance, had no effect in ankle power absorption in mid-stance but significantly reduced ankle power production in late stance, compared to the shoe only conditions (tables 6.7-6.8).

Table 6.5: Mean, standard deviation and significance value (p) for outcome measures at the ankle

	Angle		Moment		Power		
	Early stance	Late stance	Early stance	Late stance	Early stance	Mid stance	Late stance
2C	-5.53 (2.8)	22.17 (2.46)	0.27 (0.11)	-1.33 (0.17)	-0.55 (0.32)	-1.70 (0.61)	1.56 (0.51)
P value	1.000	0.040	-1.000	1.000	1.000	0.017	0.067
H3C	-4.84 (4.31)	-18.17 (3.20)	0.28 (0.12)	-1.15 (0.19)	-0.51 (0.30)	-1.38 (0.40)	1.34 (0.40)
P value	1.000	0.700	0.767	0.000	1.000	1.000	0.001
C3C	-4.95 (3.63)	19.13 (3.89)	0.25 (0.12)	-1.21 (0.16)	-0.52 (0.3)	-1.48 (0.54)	1.34 (0.43)
P value	1.000	1.000	1.000	0.023	1.000	0.699	0.004
F value	0.36	15.69	6.24	10.31	4.76	4.27	8.13
Effect size	0.07	0.76	0.28	0.78	0.24	0.20	0.32
Control	-5.69 (2.82)	19.71 (3.18)	0.24 (0.10)	-1.41 (0.15)	-0.51 (0.24)	-1.27 (0.26)	1.90 (0.49)

Table 6.6: ANOVA estimated mean peak, standard error and significance value (p) for the effect of the AFO on ankle outcome measures, when added to the shoes

	Angle		Moment		Power		
	Early stance	Late stance	Early stance	Late stance	Early stance	Mid stance	Late stance
Shoe	-5.11 (0.70)	19.82 (0.58)	0.27 (0.02)	-1.23 (0.03)	-0.53 (0.06)	-1.52 (0.09)	1.41 (0.07)
Shoe plus AFO	2.15 (0.87)	15.90 (0.73)	0.33 (0.03)	-1.19 (0.040)	-0.21 (0.02)	-1.33 (0.10)	0.61 (0.05)
P value	0.000	0.000	0.022	0.350	0.000	0.049	0.000
F value	31.50	5.49	5.90	0.70	28.69	3.30	3.69
Effect size	0.66	0.23	5.90	0.04	0.64	0.17	0.90

Table 6.7: Mean, standard deviation and significance value (p) for outcome measures at the ankle, for each shoe plus AFO condition compared to respective shoe-only condition. Adjusted p value - $p = 0.017$, N/A: the AFO did not statistically significantly affect the shoes in previous table.

	Ankle		Moment		Power		
	Early stance	Late stance	Early stance	Late stance	Early stance	Mid stance	Late stance
2C plus AFO	2.64 (3.15)	17.30 (3.47)	0.33 (0.11)	-1.24 (0.18)	-0.20 (0.08)	-1.43 (0.45)	0.88 (0.51)
P value	0.000	0.000	0.103	0.182	0.000	0.60	0.000
H3C plus AFO	1.53 (8.26)	15.18 (5.0)	0.29 (0.12)	-1.20 (0.25)	-0.51 (0.30)	-1.23 (0.59)	0.79 (0.45)
P value	0.009	0.009	0.711	0.399	0.001	0.320	0.000
C3C plus AFO	2.27 (3.25)	15.23 (3.78)	0.36 (0.13)	-1.21 (0.16)	-0.20 (0.10)	-1.33 (0.43)	0.76 (0.39)
P value	0.000	0.000	0.001	0.124	0.000	0.259	0.000

Knee

Maximum knee flexion angle in early stance and maximum knee extension angle in mid-stance were not significantly affected by any of the three rocker soled shoes (table 6.9).

The H3C significantly increased internal knee extension moment in early stance, while late stance moments remained unchanged compared to control for all shoes (table 6.9).

Knee power absorption in early stance was significantly increased by both the H3C and C3C, while the 2C caused no significant effect. Knee power in mid and late stance remained unchanged compared to control for all shoes (table 6.9).

The addition of the AFO to the C3C caused a significant increase in knee flexion angle in early stance compared to the shoe only condition (tables 6.10-6.11).

The AFO also caused a significant increase in internal knee extension moment in early stance, when combined with the 2C and C3C shoes and a significant increase

in internal knee flexion moment in late stance when combined with all shoes compared to the corresponding shoe-only conditions (tables 6.10-6.11).

Finally, the AFO caused a significant increase in knee power generation in mid-stance when combined with the 2C and C3C shoes and increased power production when combined with the H3C close to a significant level ($p = 0.019$; adjusted $p = 0.017$) compared to the shoe only conditions. Knee power absorption both in early and terminal stance remained unchanged with the addition of the AFO to all shoes (tables 6.10-6.11).

Table 6.8: Mean, standard deviation and significance value (p) for outcome measures at the knee.

	Angle		Moment		Power		
	Early stance	Late stance	Early stance	Late stance	Early stance	Mid stance	Late stance
2C	16.59 (7.63)	3.70 (5.71)	0.47 (0.22)	-0.26 (0.11)	-0.55 (0.41)	0.39 (0.19)	-0.64 (0.28)
P value	1.000	1.000	1.000	1.000	1.000	1.000	0.469
H3C	17.84 (9.14)	2.85 (5.99)	0.58 (0.24)	-0.25 (0.09)	-0.73 (0.52)	0.47 (0.25)	-0.76 (0.32)
P value	1.000	1.000	0.024	1.000	0.013	0.405	1.000
C3C	17.51 (7.64)	3.66 (6.40)	0.54 (0.22)	-0.23 (0.09)	-0.77 (0.52)	0.40 (0.22)	-0.65 (0.27)
P value	1.000	1.000	0.357	1.000	0.047	1.000	0.411
F value	1.10	1.02	7.98	1.26	4.69	1.49	1.68
Effect size	0.18	0.17	0.53	0.20	0.48	0.23	0.27
Control	16.45 (7.94)	3.27 (4.69)	-0.49 (0.21)	0.28 (0.13)	-0.51 (0.39)	0.38 (0.13)	-0.77 (0.35)

Table 6.9: ANOVA estimated mean peak, standard error and significance value (p) for the effect of the AFO on knee outcome measures, when added to the shoes.

	Angle		Moment		Power		
	Early stance	Late stance	Early stance	Late stance	Early stance	Mid stance	Late stance
Shoe	17.41 (1.85)	3.40 (1.27)	-0.53 (0.05)	0.25 (0.02)	-0.69 (0.10)	-0.69 (0.05)	0.42 (0.05)
Shoe plus AFO	21.22 (1.66)	0.80 (1.36)	-0.69 (0.05)	0.36 (0.03)	-0.78 (0.10)	-0.65 (0.06)	0.65 (0.05)
P value	0.03	0.024	0.002	0.000	0.327	0.374	0.000
F value	5.81	7.41	10.43	31.01	1.15	0.78	18.66
Effect size	0.27	0.32	0.40	0.66	0.08	0.05	0.54

Table 6.10: Mean, standard deviation and significance value (p) for outcome measures at the knee, for each shoe plus AFO condition compared to respective shoe-only condition. Adjusted p value - p = 0.017, N/A: the AFO did not statistically significantly affect the shoes in previous table.

	Angle		Moment		Power		
	Early stance	Late stance	Early stance	Late stance	Early stance	Mid stance	Late stance
2C plus AFO	21.96 (8.11)	1.02 (6.80)	0.65 (0.26)	-0.39 (0.18)	N/A	N/A	0.68 (0.27)
P value	0.091	0.33	0.015	0.001	N/A	N/A	0.000
H3C plus AFO	21.29 (8.64)	1.33 (6.05)	0.71 (0.25)	-0.34 (0.12)	N/A	N/A	0.63 (0.25)
P value	1.22	0.127	0.048	0.009	N/A	N/A	0.019
C3C plus AFO	21.41 (7.76)	1.04 (6.30)	0.71 (0.21)	-0.34 (0.14)	N/A	N/A	0.65 (0.22)
P value	0.002	0.097	0.000	0.002	N/A	N/A	0.001

Post hoc tests indicated that the increase in internal knee flexion moment was significant with respect to the control shoe for the 2C plus AFO (p = 0.017) and significant for knee power production for all shoe plus AFO conditions compared to the control shoe (2C: p = 0.000; H3C: p = 0.000; C3C: p = 0.000).

Hip

None of the rocker soled shoes caused significant changes to hip angles, moments or powers throughout stance compared to the control shoe (table 6.12).

The addition of the AFO to all shoes did not cause any significant changes compared to the shoe-only conditions (table 6.13-6.14).

Table 6.11: Mean, standard deviation and significance value (p) for outcome measures at the hip

	Angle		Moment		Power			
	Early stance	Late stance	Early stance	Late stance	Early stance	Early stance	Late stance	Terminal stance
2C	35.91 (10.05)	-3.86 (11.75)	-0.62 (0.14)	-0.61 (0.17)	0.56 (0.21)	-0.32 (0.29)	-0.56 (0.27)	0.97 (0.38)
P value	1.000	1.000	0.149	1.000	1.000	1.000	0.080	1.000
H3C	35.01 (11.02)	-3.76 (12.12)	-0.60 (0.20)	0.61 (0.22)	0.52 (0.29)	-0.37 (0.37)	-0.53 (0.33)	0.90 (0.34)
P value	1.000	0.660	0.808	1.000	1.000	1.000	0.101	1.000
C3C	34.73 (10.12)	-3.77 (11.22)	-0.57 (0.14)	0.59 (0.19)	0.45 (0.21)	-0.09 (0.21)	-0.54 (0.33)	0.87 (0.28)
P value	1.000	1.000	1.000	1.000	1.000	1.000	0.063	1.000
F value	0.25	1.73	2.08	1.32	1.41	0.45	2.84	0.85
Effect size	0.05	0.26	0.29	0.03	0.22	1.33	0.36	0.15
Control	35.10 (9.95)	-5.05 (11.80)	-0.53 (0.17)	0.61 (0.19)	0.49 (0.24)	-0.09 (0.22)	-0.59 (0.45)	0.94 (0.36)

Table 6.12: ANOVA estimated mean peak, standard error and significance value (p) for the effect of the AFO on hip outcome measures, when added to the shoes

	Angle		Moment		Power			
	Early stance	Late stance	Early stance	Late stance	Early stance	Early stance	Late stance	Terminal stance
Shoe	35.21 (2.28)	-3.80 (2.53)	0.60 (0.03)	-0.60 (0.04)	0.50 1(0.04)	-0.31 (0.06)	-0.54 (0.07)	0.91 (0.07)
Shoe plus AFO	36.47 (2.33)	-3.54 (2.65)	0.60 (0.04)	-0.61 (0.04)	0.59 (0.06)	-0.36 (0.05)	-0.55 (0.07)	0.90 (0.07)
P value	0.435	0.875	0.206	0.777	0.024	0.271	0.71	0.699
F value	0.40	0.003	1.75	0.86	6.80	0.00	1.40	0.31
Effect size	0.03	0.00	0.10	0.00	0.30	0.00	0.08	0.09

Table 6.13: Mean, standard deviation and significance value (p) for outcome measures at the hip, for each shoe plus AFO condition compared to respective shoe-only condition. Adjusted p value - p = 0.017. N/A: the AFO did not statistically significantly affect the shoes in previous table.

	Angle		Moment		Power			
	Early stance	Late stance	Early stance	Late stance	Early stance	Early stance	Late stance	Terminal stance
2C plus AFO	N/A	N/A	N/A	N/A	N/A	0.62(0.22)	N/A	N/A
P value	N/A	N/A	N/A	N/A	N/A	0.267	N/A	N/A
H3C plus AFO	N/A	N/A	N/A	N/A	N/A	0.60(0.31)	N/A	N/A
P value	N/A	N/A	N/A	N/A	N/A	0.120	N/A	N/A
C3C plus AFO	N/A	N/A	N/A	N/A	N/A	0.55(0.26)	N/A	N/A
P value	N/A	N/A	N/A	N/A	N/A	0.041	N/A	N/A

Data from the same 13 participants as in chapter 5 were analysed for the current study. As the participant number is low, the statistical power achieved for each muscle is presented and discussed in the discussion section.

EMG Peak as decimal of peak activity in the control shoe

None of the rocker soled shoes significantly affected peak tibialis anterior, medial, lateral gastrocnemius or soleus muscle activity during stance (table 6.15)(fig 6.7,6.8,6.9,6.10). Ensemble average plots (fig 6.7,6.8,6.9,6.10) did not indicate co-contraction between the tibialis anterior and triceps surae.

The addition of the AFO to all shoes significantly reduced peak tibialis anterior EMG activity. A pairwise comparisons with a Bonferroni Holm adjustment also revealed that all shoe plus AFO conditions significantly reduced tibialis anterior EMG activity compared to the control condition (2C: $p = 0.006$, H3C: $p = 0.005$, C3C: $p = 0.019$) (table 6.16). On consulting the data some evidence of possible co-contraction between the tibialis anterior and triceps surae was evident in early stance for some participants. However, due to the AFO pressing against electrodes at times, these observations may simply be due to artefact and given the low sample size that distinction cannot be made with confidence.

Table 6.14: Mean, standard deviation and significance value (p) for peak Tibialis Anterior, Medial gastrocnemius, Lateral gastrocnemius and Soleus activity. Peak activity expressed as a decimal of peak activity in the control shoe during stance.

	Tibialis Anterior	Medial Gastrocnemius	Lateral gastrocnemius	Soleus
2C	0.98(0.20)	0.94(0.15)	1.07(0.22)	1.05(0.17)
P value	1.000	0.974	1.000	1.000
H3C	1.01(0.20)	0.89(0.13)	0.99(0.25)	1.10(0.17)
P value	1.000	0.62	1.000	0.32
C3C	1.04(0.23)	0.94(0.22)	1.00(0.15)	1.05(0.17)
P value	1.000	1.000	1.000	1.000
F value	0.26	2.61	1.17	1.52
Effect size	0.07	0.44	0.26	0.31
power	0.11	0.47	0.24	0.10
Control	1.00(0.00)	1.00(0.00)	1.00(0.00)	1.00(0.00)

Table 6.15: Mean, standard deviation and significance value (p) for peak Tibialis Anterior, Medial gastrocnemius, Lateral gastrocnemius and Soleus activity, for each shoe plus AFO condition compared to respective shoe-only condition. Peak activity expressed as a decimal of peak activity in the control shoe during stance

PG. Adjusted p value - $p = 0.017$.

	Tibialis Anterior	Medial Gastrocnemius	Lateral gastrocnemius	Soleus
2C plus AFO	0.78(0.06)	1.11(0.38)	1.23(0.43)	1.14(0.41)
P value	0.003	0.151	0.110	0.373
H3C plus AFO	0.81(0.07)	1.05(0.44)	1.05(0.30)	1.29(0.66)
P value	0.001	0.208	0.419	0.265
C3C plus AFO	0.82(0.06)	1.13(0.27)	1.07(0.28)	1.10(0.58)
P value	0.009	0.554	0.220	0.757
power	0.96	0.14	0.35	0.21

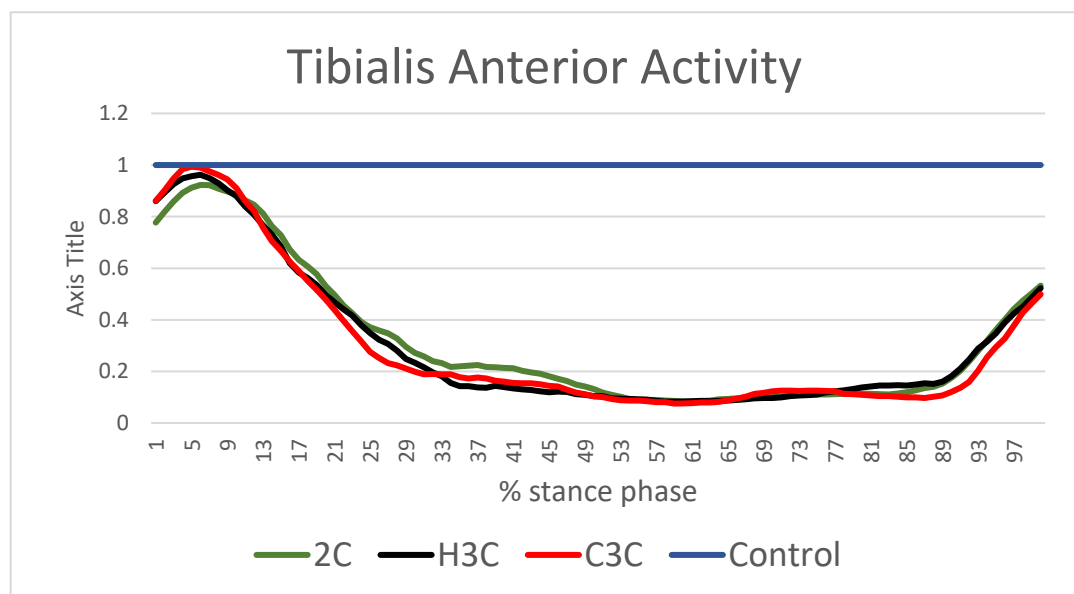


Figure 6.7: EMG activity of the tibialis anterior when walking with the 2C, H3C, C3C and Control shoe, expressed as a decimal of the control shoe peak

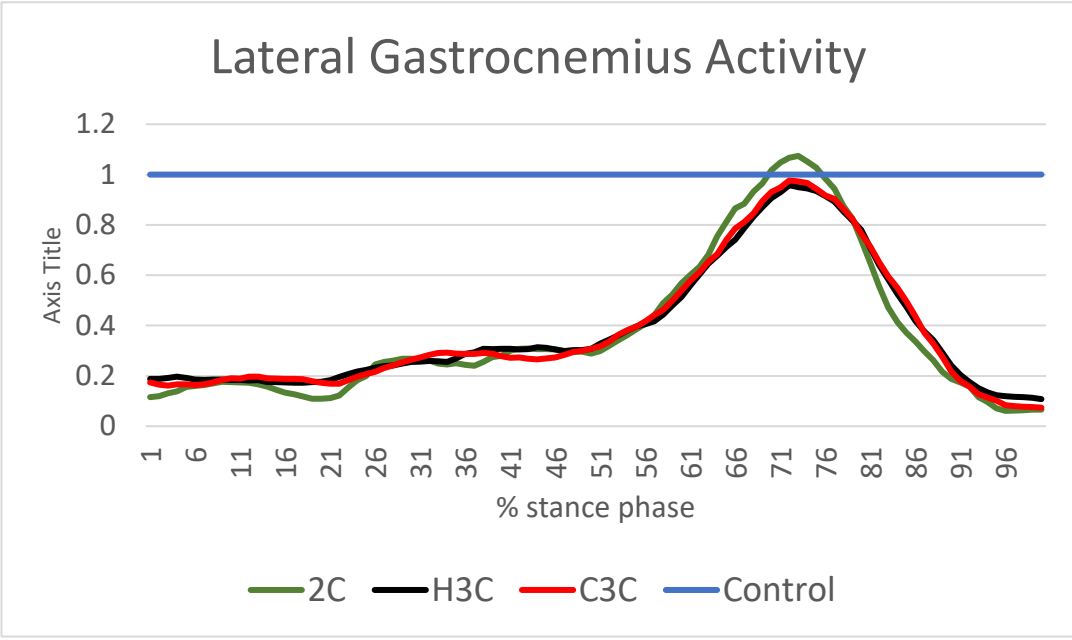


Figure 6.8: EMG activity of the lateral gastrocnemius when walking with the 2C, H3C, C3C and Control shoe, expressed as a decimal of the control shoe peak

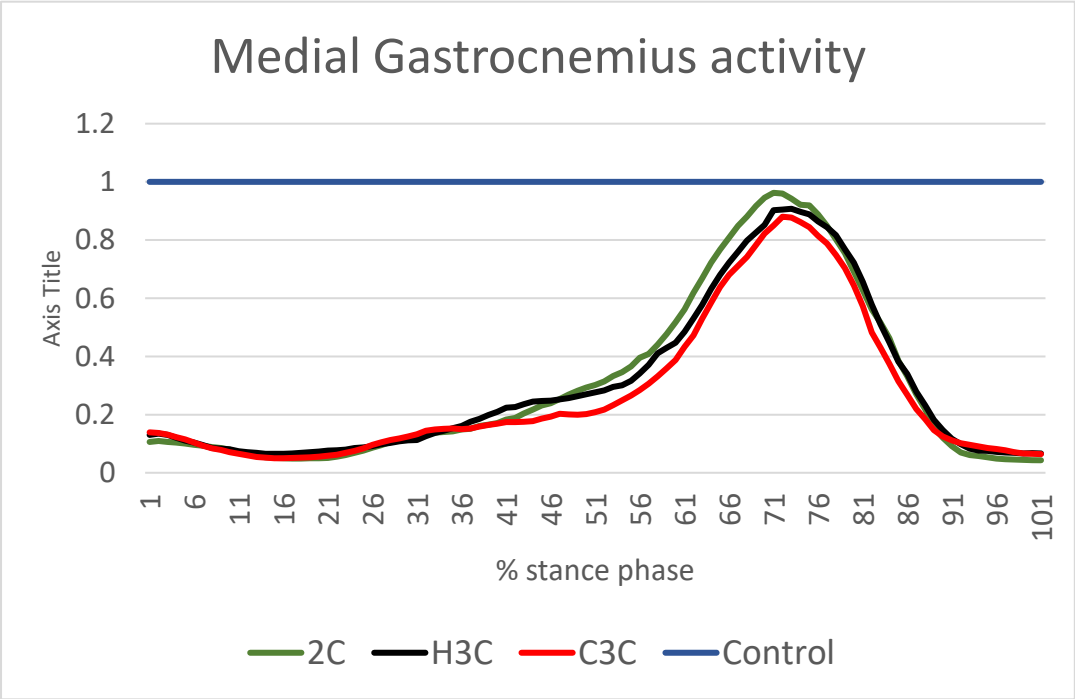


Figure 6.9: EMG activity of the medial gastrocnemius when walking with the 2C, H3C, C3C and Control shoe, expressed as a decimal of the control shoe peak

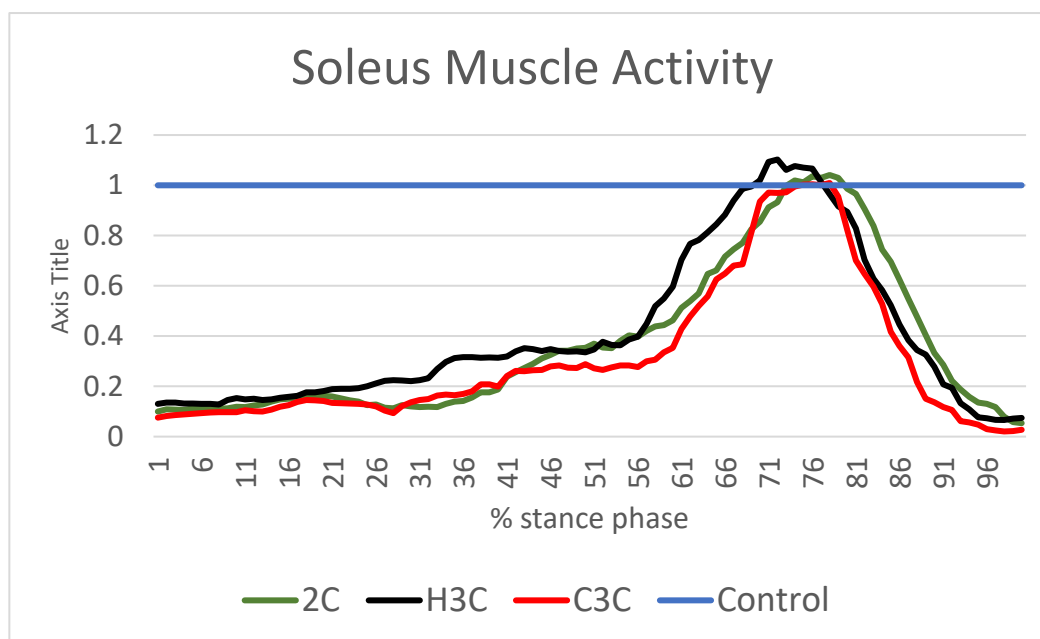


Figure 6.10: EMG activity of the soleus when walking with the 2C, H3C, C3C and Control shoe, expressed as a decimal of the control shoe peak

EMG area under the curve, expressed with regard to control shoe mean

The C3C rocker soled shoe significantly decreased the overall medial gastrocnemius work (estimated as the area under the amplitude curve) during stance, compared to the control shoe(fig 6.9). No other significant changes to work were caused by any of the rocker soled shoes on the four muscles tested (table 6.17).

The work, estimated as the area under the curve, for the shoe plus AFO conditions was not computed due to artefact from the use of the AFO in close contact with the electrodes and transmission wires. The artefacts were identified in areas of stance that did not affect the validity of the peak EMG amplitude but were judged to invalidate computation of muscle work over stance.

Table 6.16: Mean, standard deviation and significance value (p) for work of Tibialis Anterior, Medial gastrocnemius, Lateral gastrocnemius and Soleus activity. Work expressed as the integral of EMG activity curve in each muscle once this was normalised by mean activity of the control shoe during stance.

	Tibialis Anterior	Medial Gastrocnemius	Lateral gastrocnemius	Soleus
2C	29.41(9.90)	31.01(8.46)	38.33(8.71)	43.23(7.79)
P value	1.000	0.089	1.000	1.000
H3C	29.71(10.64)	30.11(7.11)	36.27(7.04)	46.56(8.66)
P value	1.000	0.058	1.000	0.224
C3C	28.46(9.37)	30.04(8.96)	34.98(7.00)	44.16(8.56)
P value	1.000	0.006	1.000	1.000
F value	0.40	6.12	1.29	2.81
Effect size	0.09	0.65	0.26	0.43
power	0.11	0.85	0.25	0.22
Control	29.64(7.19)	34.58(8.51)	35.24(10.30)	42.47(5.40)

Ground Reaction Force (GRF)

Peak posterior GRF was increased when walking with all rocker soled shoes, with respect to the control shoe. Peak anterior GRF was reduced for all rocker soled shoes compared to the control shoe.

Peak lateral GRF was significantly increased by all rocker soled shoes compared to the control shoe. No other significant changes were identified when walking with any of the rocker soled shoes (table 6.18).

The addition of the AFO to the 2C and C3C shoes caused a significant increase in first peak of the vertical GRF and medial peak of the GRF, compared to their shoe-only conditions. No other significant changes were caused by the AFO compared to the shoe-only conditions (table 6.19-6.20).

Table 6.17: Mean, standard deviation and significance value (p) for outcome measures on the ground reaction force (GRF).

	Posterior GRF	Anterior GRF	Vertical GRF peak I	Vertical GRF troth	Vertical GRF peak II	Lateral GRF	Medial GRF
2C	-0.16 (0.04)	0.13 (0.03)	1.06 (0.09)	0.82 (0.06)	1.05 (0.07)	-0.04 (0.02)	0.06 (0.02)
P value	0.016	0.000	0.322	0.037	0.112	0.007	0.708
H3C	-0.17 (0.051)	0.14 (0.03)	1.11 (0.10)	0.82 (0.09)	1.07 (0.07)	-0.04 (0.02)	0.06 (0.09)
P value	0.001	0.010	0.279	0.567	1.000	0.002	1.000
C3C	-0.17 (0.04)	0.13 (0.03)	1.09 (0.09)	0.83 (0.08)	1.07 (0.08)	-0.04 (0.02)	0.06 (0.02)
P value	0.003	0.013	1.000	0.115	1.000	0.028	0.964
F value	8.98	6.13	8.80	7.28	2.92	8.38	1.09
Control	-0.15 (0.04)	0.16 (0.03)	1.09 (0.09)	0.79 (0.05)	1.07 (0.79)	-0.03 (0.02)	0.06 (0.02)

Table 6.18: ANOVA estimated Mean peak, standard error and significance value (p) for the effect of the AFO on GRF outcome measures, when added to the shoes.

	Posterior GRF	Anterior GRF	Vertical GRF peak I	Vertical GRF troth	Vertical GRF peak II	Lateral GRF	Medial GRF
Shoe	-0.16 (0.01)	0.13 (0.01)	1.09 (0.02)	0.82 (0.02)	1.06 (0.02)	-0.04 (0.05)	0.061 (0.00)
Shoe plus AFO	-0.15 (0.013)	0.13 (0.01)	1.11 (0.02)	0.80 (0.01)	1.06 (0.02)	-0.04 (0.05)	0.066 (0.00)
P value	0.315	0.916	0.005	0.082	0.862	0.034	0.008
F value	5.57	3.61	6.38	3.11	2.15	5.68	7.51
Effect size	0.27	0.61	0.48	0.17	0.14	0.28	0.33

Table 6.19: Mean, standard deviation and significance value (p) for outcome measures on GRF.

	Posterior GRF	Anterior GRF	Vertical GRF peak I	Vertical GRF troth	Vertical GRF peak II	Lateral GRF	Medial GRF
H3C plus AFO	N/A	N/A	1.11 (0.09)	N/A	N/A	-0.04 (0.02)	0.06 (0.09)
P value	N/A	N/A	0.833	N/A	N/A	0.401	0.535
C3C plus AFO	N/A	N/A	1.12 (0.10)	N/A	N/A	-0.03 (0.02)	0.07 (0.02)
P value	N/A	N/A	0.000	N/A	N/A	0.019	0.000

The increase in peak vertical GRF in early stance was found to be significant compared to the control shoes for the H3C ($p = 0.004$) and C3C ($p = 0.004$).

Results of the decision tree:

The table below (table 6.21) presents the sum of points gained and lost by each shoe, at each level of the decision tree, as well as the final outcome in points. From these it is evident that the C3C accumulated the highest number of points, indicating it as the most effective shoe condition.

Table 6.20: Table of decision tree results at every level for the 2C, H3C and C3

2C	H3C	C3C
Level1 = no significant difference - reject	Level1 = $1.73 * 5 = 8.65$	Level1 = $1.33 * 5 = 6.65$
N/A	Level2 = $1.42 * 5 = 7.1$	Level2 = $1.42 * 5 = 7.1$
N/A	Level3 = no significant difference	Level3 = $1.39 * 4 = 5.56$
N/A	Level4 = no significant difference	Level4 = no significant difference
N/A	Level5 = $(-0.43 * 3) + (-0.56 * 3) = -2.97$	Level5 = $-0.60 * 3 = -1.80$
N/A	Level6 = no significant difference	Level6 = no significant difference
Outcome: Rejected	Outcome: 12.7	Outcome: 17.5

Questionnaire data

Notwithstanding appearance would you feel comfortable walking in this shoe during your daily activities?

When considering the shoes alone, 66.7% of participants stated that they would wear the 2C and C3C shoes and 77.8% stated that they would wear the H3C shoe. The difference in the proportion of participants willing to wear each rocker soled shoe was not significant ($p = 0.607$).

When asked if they would use the shoe plus AFO combination the percentage of participants who answered positively was reduced to 55.6% for all shoe plus AFO conditions. This increase was not significant for any of the shoe plus AFO conditions compared to their respective shoe only conditions (2C: $p = 0.157$; C3C: $p = 0.48$; H3C: $p = 0.157$).

How stable do you feel when walking along a smooth surface with this shoe compared to your normal footwear?

Table 6.21: Participant numbers in answer to question regarding instability of the rocker soled shoes and shoe plus AFO conditions.

	1 Very unsteady	2	3	4	5 No feeling of unsteadiness
2C	1	2	4	8	3
2C plus AFO	1	6	4	5	2
H3C	1	2	4	5	6
H3C plus AFO	3	0	7	2	6
C3C	3	0	7	2	6
C3C plus AFO	3	2	6	3	4

The table above represents the number of participants that chose each number of the 1-5 Likert scale for feeling of unsteadiness with each of the seven interventions (table 6.21). No significant differences were identified among shoes ($p = 0.093$). The

addition of the AFO to the C3C and H3C shoes did not significantly alter the perception of participant stability as they walked ($p = 0.025$; $p=0.025$; adjusted $p = 0.017$). However, the addition of the AFO to the 2C shoe significantly increased their perception of stability ($p = 0.004$). No significant differences were identified among shoe plus AFO conditions ($p = 0.029$, post hoc tests with adjusted p at 0.017 indicated: 2C plus AFO –H3C: $p = 0.035$; H3C plus AFO-C3C plus AFO: $p = 0.025$; 2C plus AFO-C3C plus AFO: $p = 0.414$).

6.5 Discussion

This thesis is predicated on an assumption that reductions in ankle moments, powers and EMG should translate to an increased maximum pain-free walking distance in individuals with PAD-IC. The scoring of the shoes based on the decision tree demonstrated that the 2C rocker shoe is not effective at reducing outcome measures in a way that could be beneficial to these individuals. Its lack of beneficial effects on ankle moments and powers, coupled with the lack of effect on the calf muscles, make it an ineffective choice for individuals with PAD-IC.

In contrast, both the C3C and H3C shoe demonstrated effectiveness at reducing ankle dorsiflexion moments and powers in late stance and thereby beneficially altering outcome measures. Both the C3C and H3C were three curve rocker soled shoes, with the C3C having larger curve radii than the H3C. At the level of the ankle, the H3C and C3C did not significantly differ with respect to one another in the effects produced. However, the increase in knee flexion moment in early stance by the H3C along with its lack of significant effect on the calf muscles compared to the C3C, indicate that the C3C is likely the overall most effective shoe for individuals with PAD-IC.

The addition of the AFO to the shoe produced a significant added benefit at the ankle and on peak tibialis anterior muscle activity for all shoes. However, the significant increase in late stance knee extension moment, when the AFO is added

to all shoes, and the significant increase in late stance knee power and early stance knee flexion moment for the when combined with C3C plus AFO and 2C plus AFO make the use of the AFO potentially risky. Consequently, the use of AFOs might be best placed only if shoe effects prove insufficient in terms of improving walking distance, and after the design of the AFO has been reconsidered.

The following is a more detailed and critical discussion of the results in the context of PAD-IC gait with the intention of determining the most effective shoe or shoe plus AFO combination for the next study in chapter 7.

Ankle & EMG

At the level of the ankle the 2C rocker shoe did not bring about any significant beneficial effect and indeed negatively affected ankle power in mid-stance. It can therefore be discounted as a potential footwear design to increase PAD-IC pain free gait. However, the current findings contrast with those of Hutchins et al (Hutchins, 2007), who tested the 2C rocker design and reported a significant reduction in ankle dorsiflexion angle in mid-stance, external ankle dorsiflexion moment and external knee extension moment in mid to late stance, and a significant increase in knee power absorption in mid-stance. This discrepancy might be due to Hutchins's use of young healthy individuals whereas the current study used volunteers with PAD-IC. Along with the work in chapter 5 of this thesis, research has shown significant differences between the gait of younger and older adults and older adults with and without PAD-IC (Koutakis et al., 2010a, Wurdeman et al., 2012, Koutakis et al., 2010b, Chen et al., 2008, Celis et al., 2009, Crowther et al., 2007, Gommans et al., 2016). Therefore, the work of Hutchins excludes the effect of both age and PAD-IC on his results. Several studies, including the one in chapter 5, have shown that individuals with PAD-IC walk slower and with a smaller step length than healthy individuals. The effect of the rocker soled shoe is connected to the walking speed because walking velocity assists in the movement of the foot through stance by supplying an angular acceleration to the shoe, which causes it to rotate. This is due to the sole of the shoe sole being generally elliptical in design and walking velocity

acting upon it. Velocity acts on the sole as a moment from the proximal body structures. Since the shoe is elliptical in nature, when a moment acts upon it, the shoe will roll under an angular acceleration produced by the moment.

$$\Sigma M = I * \alpha ; \alpha = \text{angular acceleration}; I = \text{moment of inertia}; M = \text{moment}$$

The smaller the velocity of the individual the smaller the angular acceleration of the shoe will be. Therefore, the effect that rocker footwear will have on groups of people walking at different speeds will differ. Since healthy individuals walk, on average, faster than individuals with PAD-IC, this may be the reason for the disparity in results between the current study and that of Hutchins.

Furthermore, in Hutchins et al (2007) work, the 2C rocker soled shoes were based on curves with radii from the floor to just below the ankle and hip (without the offset for the height of the shoe being applied). Therefore, the resulting shoes would have generated a smaller shoe to ground angular acceleration from the same walking velocity, compared to the H3C and C3C (which have smaller radii and therefore more acute curves). Given the smaller speed of the PAD-IC patient group compared to healthy individuals (and therefore the participants in Hutchins's study) the effect of the shoe would be further diminished for people with PAD-IC. This agrees with the results of the 2C in the present study.

$$\text{angular acceleration} = \text{linear acceleration} / \text{radius}$$

If we assume same linear acceleration, for all shoe conditions, because of same walking velocity and stance time, the smaller the radius the greater the angular acceleration will be.

$$M_{ankle} = (I * \alpha) - M(grf) - (F(grf) * d1) + (d2 * (a - g))$$

The formula above, used for the computation of ankle moment by visual 3D shows that by increasing angular acceleration (α) the moment in late stance will be reduced (where M_{grf} is the moment created by the ground reaction force, F_{grf} is the ground reaction force, d_1 is the perpendicular distance from the centre of mass of the foot to the point of application of the ground reaction force, d_2 is the perpendicular distance from the ankle joint to the centre of mass of the foot, a is linear acceleration, g is acceleration due to gravity, α is angular acceleration of the foot and I is the moment of inertia of the foot)(fig 6.11).

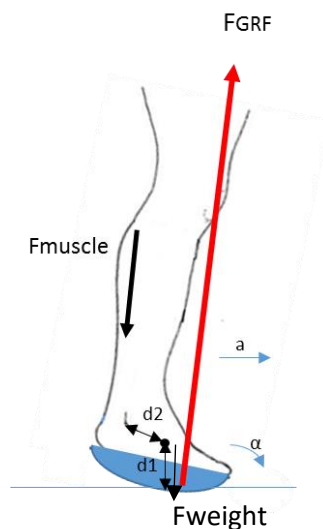


Figure 6.11: Main forces acting on lower limb in late stance phase of gait.

This may indicate that at slower walking speeds, such as those of individuals with PAD-IC, a steeper curve than that of the 2C rocker is necessary to ensure that the angular acceleration of the foot is sufficient to significantly reduce ankle dorsiflexion moment in late stance and thereby the force required by the muscles.

Moreover, since in the 2C shoe there is only an arc transition at the ankle, from small arc to larger arc, (from the first curve centred just below at the ankle to the second centred just below the hip) and not under the metatarsal heads (as in the H3C and C3C), there would be no further increase in the angular acceleration of the foot-shoe during push off. This could be important because this is the time when the gastrocnemius reaches its peak activity. Instead, after the junction between the two arcs at the ankle, the *shoe-foot* segment (these are treated as one by visual 3D and in the current analysis since we assume only minute movement of the shoe inside the foot) will gradually gain angular momentum due to the sole curve during

stance. However, due to the larger 2nd radius of the 2C shoe, the shoe's angular acceleration will be smaller than either of the three-curve rocker soled shoes for the same walking velocity.

Contrary to the 2C shoe, both the H3C and C3C significantly reduced ankle dorsiflexion moment and ankle power generation in late stance but there was no significant difference between the shoes. It is difficult to put the reductions in ankle moments and power into context, such as whether the reductions are sufficient for longer walking or closer to the capability of the muscles (such that demand and delivery of oxygen in the blood might be better matched). However, previous research has shown that individuals with PAD-IC have lower peak isokinetic internal plantarflexion torque (by 0.17Nm/Kg) compared to healthy age-matched counterparts (Câmara et al., 2012). Both the C3C and H3C reduced the external dorsiflexion moment, and thereby internal plantarflexion torque by 0.20Nm/Kg and 0.26Nm/Kg respectively. The average internal plantarflexion moment was less than the average peak isokinetic torque achieved by people with PAD-IC reported by Camara et al (2012) (0.21Nm/Kg and 0.15Nm/Kg vs 0.36 Nm/Kg. This suggests that both shoes are capable of reducing external moments at the ankle to a level where the peak internal demand moment is below threshold values for this group of patients.

The lack of significant difference between the two variations of three-curve rocker shoe is perhaps an indicator of the ability of the lower limb to tolerate variations in the curve radii. Specifically, the curve radius for the C3C was on average 3cm greater than that of the H3C, to account for the thickness of the shoe sole. Therefore, the resulting sole had milder curves (by approx. 5.6°) and was slightly thicker, by an average of 2 mm. This would have resulted in a slightly smaller angular acceleration of the C3C shoe. However, this difference in shoe radii did not prove sufficient to significantly alter the effect at the ankle between the shoes. This apparent tolerance of small variations in sole curvature may indicate that creating sole arcs with centres at the lower limb joints on a patient by patient basis is not necessary. This would shift the focus in PAD-IC shoe design from lower limb

anatomy to the angular acceleration of the shoe, its effects on PAD-IC gait and the correlation of their assisted (by the shoe) gait with that of healthy counterparts.

EMG results indicated the C3C shoe statistically significantly reduced the overall work of the medial gastrocnemius compared to the control, while the H3C caused no such significant reduction, despite the two shoes causing similar kinetic effects at the ankle. Medial gastrocnemius work did not differ significantly between the C3C and H3C conditions ($p = 1.000$). Therefore, the C3C likely has a small advantage in reducing this muscle's work compared to the H3C, which was itself able to cause a significant reduction with respect to the control shoe.

As stated above, the H3C shoe is designed with steeper sole curves compared to the C3C, which would translate to a slightly smaller base of support for the H3C compared to the C3C. This would mean that the centre of mass of the individuals would move outside the base of support more quickly in the H3C shoe than the C3C. Furthermore, due to the reduced radii of the H3C, the angular acceleration of the shoe would be slightly greater. Therefore, it is possible that the angular acceleration of the foot-shoe, and therefore the progression of the centre of pressure on the sole was such that participants' centre of mass moved in front of the centre of pressure on the foot to a degree that was not considered acceptable or safe. This may have caused them to control the motion in order to avoid a perceived fall. In turn, this would translate to greater eccentric contraction of the gastrocnemius throughout stance, which would assist the soleus in maintaining stability, and would explain the lack of significant difference between the peak medial gastrocnemius activity of the C3C and H3C, when the work of the C3C was slightly reduced. Within the questionnaire, more participants reported a mild fear of losing stability in the C3C compared to the H3C, and a slight preference for using the H3C (66.7% vs 77.8%) although this difference was significant.

Neither the C3C nor the H3C had any significant impact on the work of the remaining muscles nor on peak activity of those muscles throughout stance. However, whilst not statistically significant, mean total work of both the medial and lateral gastrocnemius were reduced for the C3C and H3C, and there was only a small

increase in mean for the soleus. This indicates that both shoes have a tendency to reduce the overall activity of the gastrocnemius throughout stance.

However, this raises the question of why the shoes are capable at reducing the overall activity of the muscles but not the peak. The reason for this may be that the people wearing the shoes need a longer period of time to get accustomed to them. Specifically, the fact that the C3C and H3C might be able to reduce the moment required at the ankle by the calf muscles, does not mean that the people wearing the shoe will reduce the amount of force generated by the calf muscles immediately. A longer acclimatisation period than the 5 minutes offered, which may range from hours to days, may be required for the neuromotor system to adjust the force output from these muscles, and for the true effect of the rocker soles to be seen. This was not attempted in the current study firstly because it was a pilot test of the shoe and, secondly, because the shoes had not yet received CE approval and could not be given to participants to test outside the University laboratory.

For example, in his first study Hutchins tested gastrocnemius, soleus and tibialis anterior muscle activity for the H3C and reported no significant difference compared to a control shoe (Hutchins, 2007). However, a second study on pain-free walking distance with the H3C, in individuals with PAD-IC, indicated a significant increase of 34.8 meters with the H3C compared to a control shoe, which one can argue is a clinically significant increase (Hutchins et al., 2012). The real-world effectiveness of the shoes in increasing the walking distance of individuals with IC will need to be determined in a separate study (chapter 7).

The addition of the orthotic did not alter the ability of either the H3C or C3C to reduce ankle dorsiflexion moment in late stance. However, compared to the equivalent shoe only conditions it significantly reduced ankle power generation in late stance, as well as ankle power absorption in early stance. However, the AFO significantly increased ankle plantarflexion moment in early stance when paired with the C3C shoe but significantly reduced peak tibialis anterior activity when paired with all shoes.

The significant increase in peak early stance ankle dorsiflexion moment with the C3C plus AFO is, at first glance, contradictory to the significant reduction in peak tibialis anterior activity for all AFO conditions. However, the inverse dynamics used to calculate moment in Visual 3D does not differentiate between internal moment produced by the muscles and moment produced by the AFO.

If we examine the findings beginning with external moment, all three rocker soled shoes significantly increased peak posterior GRF in early stance compared to the control shoe. This increase alone will cause an increase in the angle of the GRF to the ankle, and thereafter the external plantarflexion moment arm, and moment. When adding the AFO this increase in posterior GRF remained (the orthotic did not significantly change peak posterior forces but the first vertical GRF peak was also significantly increased (for 2C plus AFO and C3C plus AFO). This increase would further add to the external ankle plantarflexion moment and internal moment.

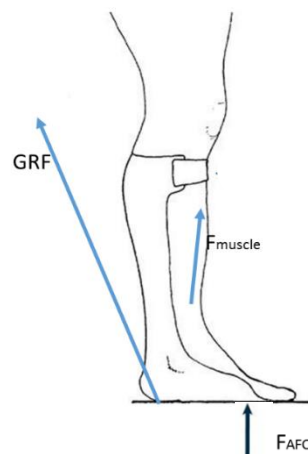


Figure 6.12: Image depicting reaction force of AFO on the foot.

The AFO generates a force that acts perpendicular to the plantar surface of the foot when an internal or external force attempts to plantarflex the ankle (fig 6.11). This force will create a moment at the ankle which in early stance is opposite to that of the GRF which is attempting to plantarflex the ankle. Therefore, in reality, the internal ankle moment can be reduced because of the stiffness of the AFO and the dorsiflexion moment it applies at the plantar surface of the foot. The fact that internal ankle dorsiflexion moment was reduced in early stance, is supported by the

reduction in peak tibialis anterior activity for all three shoe plus AFO conditions. The reason for the reduction in ankle power in early stance is most likely the reduction in angular velocity of the ankle due to the reduced ankle range of motion.

A reason for the difference between ankle moment and peak calf muscle EMG data, in late stance, for the three shoe plus AFO conditions may lie in the effect of the AFO on ankle motion. The AFO significantly reduced ankle motion with respect to the shoe-only conditions. The angular velocity of the ankle and thereby ankle power would therefore be reduced (which is why muscle activity would be expected to be reduced, because concentric and eccentric motion of the muscles are restricted). However, the fact that the ankle joint and consequently the eccentric and concentric contractions of the calf muscle are restricted does not necessarily lead to a lack of calf muscle activity. For example, the bi-articular gastrocnemius can eccentrically contract during motion of the knee, and the remaining muscles are still able to contract isometrically and co-contract with their antagonist muscles in order to maintain stability. If participants perceived a threat to their balance, whether consciously or subconsciously, this may have lead them to attempt to recruit the triceps surae in late stance, not to produce sufficient force for push-off but to slow the progression of the CoP instead.

Overall, therefore, the addition of the orthotic caused significant positive effects at the ankle compared to the shoe-only conditions which were however not mirrored by EMG findings. However, a shoe-orthotic combination is a more bulky and intrusive intervention than a shoe, is less aesthetically pleasing and is associated with poorer patient compliance (Vinci and Gargiulo, 2008). Statistical analysis of the questionnaire answers did not highlight any significant decrease in sense of stability, or significant increase in non-acceptance of the shoe plus AFO combinations in comparison to the shoe only conditions. However, on average 44.4% of participants in the current study stated they would not wear the AFO combined with any of the shoes, compared to 34.6% for the 3C and C3C and 24.6% for the H3C shoes on their own.

Participants also verbally voiced their dissatisfaction when wearing the AFO, irrespective of which shoe it was combined with. They voiced their sense of a lack

of control during gait due to the level of movement restriction, as well as discomfort around the ankle and foot due to the fit. Having a shoe that provides slightly less benefit than a shoe-orthotic combination is therefore perhaps more desirable. In this sense the C3C shoe provides the most benefit at the ankle.

It is important to highlight that non-significant EMG findings were associated with low powers, which reflects an insufficient sample size. The significant reductions in tibialis anterior activity for the shoe plus orthotic conditions and significant reduction in the overall gastrocnemius activity during stance were appropriately powered and can be confidently considered true effects of the interventions. However, the lack of observed effects on other muscles cannot be confidently concluded due to the sample size. It may therefore be that with a larger sample size, the significant reduction in ankle moment caused by the AFO in late stance would become associated with a significant reduction in gastrocnemius and/or soleus activity. Similarly, other discrepancies between kinetics and EMG findings, such as the reduction in ankle moment for the C3C and H3C shoes, which were not mirrored by a reduction in peak gastrocnemius or soleus activity during stance, may be the result of an insufficient sample size. It might equally reflect the fact that EMG signals are not a direct measure of forces produced by muscles, rather a surrogate of this based on a sample of muscle fibre electrical activity. The power of these outcome measures in the current study does not allow for such a conclusion or inference to be made at present. Future studies will have to investigate these effects further in a larger sample of participants for such a conclusion to be confidently reached.

Knee

Changes at the level of the knee, although not as significant for the purpose of increasing pain-free walking distance, are of importance. Specifically, it was imperative to ensure that while attempting to reduce the work done by the calf muscles, no unwanted effects at the knee were caused by the interventions.

Substantial increases in moments and/or powers (which will require additional muscle effort to counteract) may strain the knee joint structures, either by forcing an increase in the range of motion or by increasing the demand for force production on the quadriceps and hamstrings. These are large muscle groups and when their demands increase they require an increased blood (and thereby oxygen) supply. Since these muscles are proximal to the calf muscles, when their demand for oxygen increases, this will reduce the amount of oxygen reaching the calf muscles. Thus any beneficial effects at the ankle, and reduction of calf muscle activity, could be cancelled out by a further reduction in oxygen supply to these muscles due to changes at the knee.

Only the H3C shoe statistically significantly affected knee moments, increasing knee flexion moments in early stance. This reflects either a higher GRF or an increase in the moment arm in early to mid-stance (i.e. the GRF may have passed more posterior to the knee joint compared to the control shoe condition). Findings in GRF data indicated an increase in peak posterior GRF for the H3C which may be part of the reason for the increase in early stance knee flexion moment. However, the peak posterior force was significantly increased for all three rocker soled shoes compared to the control. Therefore, the H3C must cause the GRF to be positioned more posteriorly (i.e. longer moment arm) too. As the aim of the footwear is to reduce the demand for force from the lower limb muscles (primarily the calf, but proximal muscle groups as well) this increase can be considered a shortcoming of the H3C.

Knee power absorption in early stance was also increased by the H3C and C3C shoes but not the 2C shoe, indicating an increase in angular velocity as the knee flexes under a flexion moment, coupled with the greater peak posterior GRF identified. As both the C3C and H3C shoes are designed from curves with smaller radii than the 2C shoe (and will therefore have greater shoe angular acceleration), it is understandable why only the former two would cause the potential increase in ankle angular velocity. The increase in power absorption is an unwanted effect, but less so than power production, because absorption is related to eccentric

contraction of the muscles which is a smaller contraction in magnitude compared to concentric contraction.

Adding the AFO caused a significant increase in early stance knee flexion moment for the 2C and C3C shoes and a significant increase in mid to late stance knee extension moment for all shoes. This was mirrored by a significant increase in knee power generation in mid-stance for the 2C and C3C and a close to significant increase H3C ($p = 0.019$). Post hoc tests revealed that the increase in knee moment was significant with respect to the control shoe for the 2C plus AFO ($p = 0.017$) and significant for knee power production for all shoe plus AFO conditions compared to the control shoe (2C: $p = 0.000$; H3C: $p = 0.000$; C3C: $p = 0.000$).

The increase in knee moment and power in mid-stance is an effect of the redistribution of forces by the AFO. The force at the level of the shank strap on the AFO prevents the ankle from dorsiflexing during mid- to late stance and causes the knee to extend in order to allow the body's centre of mass to continue to move forward. In cases where there is weakness and pain at the calf muscles, sufficient to cause knee flexion instead of extension during this period and a reduction in knee power generation in mid-stance (which was not the case for individuals with PAD-IC since a significant increase was observed ($p = 0.000$)) this function of the AFO is beneficial. However, since this is not the case for the patient group under examination, and since their gait is assisted by the rocker soled shoes, the increase in extension moment and power production in mid to late stance are negative findings.

Previous research has shown significant degradation of the lower limb muscles of individuals with PAD-IC (England et al., 1992, Regensteiner et al., 1993). Since the muscles are structurally weaker, the increases in moment and power observed at the knee may cause an increase in the forces which need be produced and absorbed, and possibly causing unnecessary strain to the knee joint structures, leading to trauma. Furthermore, an increase in power production at the knee indicates an increase in the demand on the hamstrings and quadriceps. As mentioned above, an increase in the demand for oxygen in these muscles suggests a reduction in the available supply to the calf muscles, which opposes the aim of

the footwear. Therefore, the findings indicate the orthotic tested may not be an appropriate intervention for this patient group.

A more flexible orthotic to restrict the ankle, such as a posterior leaf spring AFO, could result in greater beneficial effects than the C3C alone, without risking the integrity of the knee structures or imposing greater demands for oxygen proximally. The details of optimal AFO design are outside this current thesis but could be the subject of future work.

Hip

It was important to investigate any effects of the footwear at the level of the hip because this too would affect proximal demand for oxygen and could indicate potential unwanted kinetic effects of the shoes. This is especially important since the muscles of the hip are some of the largest in the body (e.g. gluteals). Ideally, as at the knee, hip moments and powers, should either not be altered or be reduced by the shoe conditions. This would be evidence that the work required at the level of the ankle was not being transferred proximally. Encouragingly, there were no effects at the hip for any of the shoes or with the addition of the AFO.

Limitations

The current study consisted of walking in three rocker soled shoes (2C H3C, C3C), the sole of which was thicker and slightly heavier than everyday shoes. Whilst the shoe uppers were kept identical between shoes, these were low cut (below the ankles) and this resulted in the weight of the shoe causing the heel of several participants to lift within the shoe as they walked. When this was reported by participants a heel grip insert was added to the shoes prior to data collection. This insert consisted of low density VA material (35 degrees shore A) and was thick 7mm thick and was stuck to the back of the shoe with double sided tape. This was chosen instead of an off the shelf heel grip because the thickness of the material ensured little to no heel slipping and this could be customised to each participant's needs.

It is possible that the inserts used were not absolutely successful in preventing heel slipping and this may have influenced study findings. However, every possible effort was made to ensure that this was not the case.

Furthermore, it is understood that, for the full effect of a rigid AFO to be applied to the foot, the AFO should be custom made, to ensure that the material covers the malleoli and that the fit is optimum. It is therefore accepted that the AFOs used in the present research may not have had the same level of effect on all participants when walking in the shoe plus AFO conditions. However, the goal of the present research was to determine whether a prefabricated mass-produced intervention, not a custom made one, could cause significant changes in the lower limb kinetics and muscle activity of individuals with PAD-IC and, in turn, significantly increase their walking distance. As with any such intervention, not all individuals in the target population will benefit equally from its use, but it is important to determine whether, on average, the effects that it evokes are significant. Consequently, the variability that the AFO introduces is a known and rather desirable factor.

6.6 Conclusions

The C3C is the most effective shoe at producing beneficial changes in gait kinetics and EMG of individuals with PAD-IC, which should in turn increase their pain-free walking distance. The addition of an orthotic was rejected due to its negative effects on knee moment and power, its lack of significant benefit on muscle activity, and the negative feedback received by participants. Therefore, the C3C shoe was chosen for further study of its clinical effectiveness and investigated in the next chapter.

Chapter 7. Real world effects of the C3C

7.1 Introduction

This chapter investigated the real-world effects of the most beneficial footwear design identified in the previous chapter (C3C shoe). Studies one and two served to identify the alterations in gait caused by PAD-IC, followed by investigation of the most effective shoe condition for decreasing calf muscle activation and moments and powers at the ankle. This chapter focuses on linking the altered moments and reduced EMG activity previously identified during a laboratory-based study, with functional performance under more real-world conditions. From the results in chapter 6, the C3C shoe should, in theory, increase the pain-free and maximum walking distances of individuals of PAD-IC. However, this hypothesis has not been tested previously and laboratory studies, although allowing for the collection of accurate quantitative parameters, do not represent the environments most often encountered by the clinical population in the real world. Therefore, it is possible that the biomechanical effects of the C3C are not sufficient to produce a significant clinical benefit in terms of walking distance. The current study serves as a first pre-clinical test of the C3C and its effectiveness in situations and tasks which are closer to those encountered in the real world.

To examine the effectiveness of the C3C compared to control shoe in a real word situation, calf muscle activity, time and number of steps taken whilst traversing stairs and an outdoor inclined pathway are compared. Secondly, the maximum walking distances of PAD-ICs in both shoes are compared.

Furthermore, a large proportion of individuals with PAD-IC suffer from diabetes as the most common co-morbidity. This population can be at risk of plantar foot ulcers if pressures are elevated under to foot. It was therefore imperative to assess the effect of the shoes on plantar pressure so as to ensure that, should these shoes prove to offer a clinical benefit in terms of pain free walking, they are safe to be worn by people with diabetes as well as PAD-IC. To address this issue plantar pressures when walking with the C3C and a control shoe were investigated.

7.2 Aim and Objectives

Aim: The study had two main aims:

1. Test the effectiveness of the preferred rocker soled shoes in a real world rather than laboratory environment:

Objectives:

- Assess maximum walking distance in a control shoe and the C3C shoe
- Assess calf muscle activity in both shoes

2. Determine the safety and efficacy of the shoe in real world environments

Objectives:

- Assess plantar pressures in the control shoe and the C3C
- Assess patient perceived safety and patient perceived confidence in stair climbing and angled surface walking tasks with the rocker soled shoe

7.3 Methods

Participant recruitment received approval from the University ethics committee (Number HSCR13/91) and the North West - Greater Manchester South Research Ethics Committee (Number 16/NW/0139). Participant identification recruitment followed the same procedure as the one outlined in chapter 5.3.1

7.3.1 Inclusion criteria

A priori power size calculations, using data from Sacco et al, 2012, and Chapman et al 2016, indicated sample sizes of 9 for EMG data and 17 individuals for planter pressure data accordingly (to achieve power of 0.8). Therefore, 18 Individuals with PAD-IC were recruited for the purposes of the study. Individuals with PAD-IC were included in the study if they had a clinical diagnosis of peripheral arterial disease (PAD) and intermittent claudication (IC). Participant identification took place in hospitals and clinics in the greater Manchester, area after receiving University, NHS (National Health Service) and MHRA (Medicines and Healthcare products

Regulatory Agency) ethical approval. Clinical diagnosis was confirmed by either vascular consultants or other hospital staff with regular access to medical records of potential participants. The participant recruitment method was the same as the one analysed in chapter 5.3.1.

7.3.2 Exclusion criteria

Individuals who had active foot ulcers, significant foot deformities necessitating use of foot orthoses, or sciatica were excluded from the study.

7.3.3 Study design

Eighteen individuals with intermittent claudication, fitting the inclusion criteria were admitted into the study. Participants were given time to familiarise themselves with the lab, and offered the consent form. Provided they provided consent they were asked to change into a pair of tracksuit bottoms and to lie down on a medical bed where EMG electrodes were placed on the calf muscles of their self-reported most affected limb (i.e the one to claudicate first when walking) according to the methods used in section 4.1 & 4.2.3.b. The wireless DTS Noraxon DTS system (Desktop DTS, 586, Scottsdale, Arizona 85260) was used for data collection (fig. 7.1).



Figure 7.1: Noraxon, DTS system

Following this, participants were asked to walk up and down an outdoor 50 metre 15 ° angled walkway (as this is a commonly used walkway by University students, staff and visitors) at their comfortable walking speed, wearing the C3C and control shoe. As they walked EMG, number of steps and walking time were recorded. Participants were then brought indoors and asked to walk up and down a flight of 21 stairs (well lit, with railing and slip proof strips) in both shoes. In all testing tasks participants wore the C3C and control shoe in a pre-randomised order (using an online randomisation tool: www.randomizer.org).

Pedar insoles were inserted consecutively into both types of shoe to assess plantar pressures when walking in a straight line indoors. The insoles were connected, via, wires, to a transmitter which was secured onto a neoprene belt that participants wore around the waist. This transmitter sent data on plantar pressure, collected by the insoles, to the Pedar software on a laptop. A detailed analysis of the methodology used in data collection and analysis of plantar pressures can be found in appendix A.

Participants were asked to perform 6 consecutive walks along an eight-metre walkway with the control shoe and C3C shoe, in the pre-randomised order, staying within 5% of their average speed. Average speed was determined using five walks, performed before the start of data collection, with one of the shoes at random. After completing 6 walks in each shoe the insoles and belt were removed and participants were asked to take five minutes of mandatory seated rest.

They were then asked to walk again, this time at their self-selected speed, in both pairs of shoes for 6 minutes consecutively (a common physical examination tests used by physicians to grade the severity of IC), to mention when their pain was first felt and to rate it on a scale from one to four, as it increased, (according to the scale used in NHS exercise programs) (fig. 7.2) until they reached their maximum walking distance (i.e the point at which they needed to stop walking due to severe pain/discomfort).

Average peak EMG, number of steps taken and duration of walking (minutes:seconds) until the moment they needed to stop due to claudication pain

(maximum walking distance) were collected. The time taken to reach each point on the pain scale was also recorded. Between the two 6-minute walks, participants were given ten minutes of seated rest. Finally, participants were asked to fill in a short questionnaire on the perceived safety and effectiveness of the rocker soled shoes. Within the questionnaire, the outdoor inclined walk way was referred to as a ramp.

Intermittent Claudication Rating Scale
0 No claudication pain
1 Initial, minimal pain
2 Moderate, bothersome pain
3 Intense pain
4 Maximal pain, cannot continue

Figure 7.2: Intermittent claudication pain scale, used by Salford Royal exercise clinic.

7.3.4 Data analysis

EMG

The raw EMG signal for the tibialis anterior, medial gastrocnemius, lateral gastrocnemius and soleus muscles of the most affected limb were analysed using Noraxon M3.8 software. Specifically, the signals were full wave rectified, high-pass filtered at 20 Hz, low-pass filtered at 500 Hz smoothed using an RMS filter with a window of 80. The data were then exported to excel. For each activity (6 minute walk test, Pedar walk, walk up ram, walk down, ramp, walk upstairs, walk down stairs) the mean activity for each muscle in the control shoe was computed. All signals were then normalised to the mean activity for each muscle for each activity in the control shoe. The normalised signals were imported into Matlab and using a custom script peaks for each muscle throughout the activity were identified. These were then exported into excel and averaged to find the mean peak.

Pedar

Pressure data was collected in Pedar® software. Data was then exported to ascii file format and imported into matlab for further processing. Using a script masks, describing regions of the plantar surface of the foot, were assigned to regions of the pedar insole, for the hallux, phalanges, first metatarsal head, 2nd-4th metatarsal head, 5th metatarsal head, midfoot and heel (fig. 7.3). An analytical explanation of the pressure analysis methods used can be found in appendix A. Maximum plantar pressure in each mask for each participant throughout the walk was computed for each shoe condition. The data for each participant was exported to excel and collated for all participants.

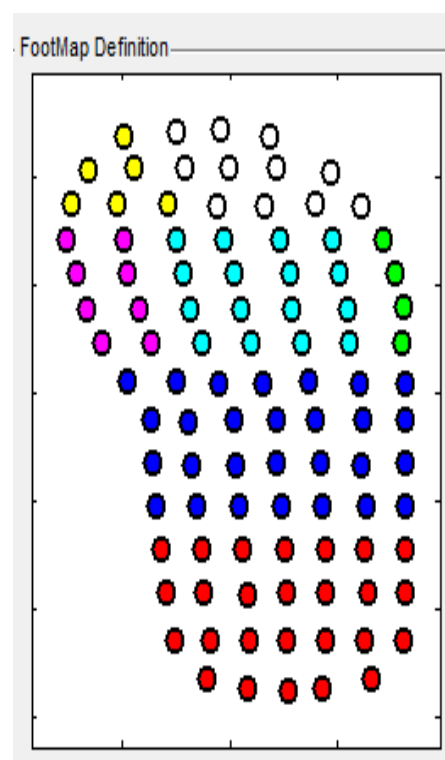


Figure 7.3: Foot masks used to identify regions of the plantar surface of the foot and their pressure. Yellow: Hallux; White: Toes; Purple: First metatarsal head; Light blue: Second to Fourth metatarsal head; Green: Fifth metatarsal head; Blue: Midfoot; Red: Heel

Questionnaires

The answers from each questionnaire question were input into excel with their appointed code number and the average answer to each question computed.

7.3.5 Statistics

Paired t-tests were performed for the maximum pain-free and ultimate walking distances between the two shoe conditions. These were also performed to test the difference in means of the peak plantar pressures in each mask between the two shoes as well as the peak EMG between shoes for each muscle, while performing all tasks of the study. Where data was found not to follow a normal distribution, the Wilcoxon non-parametric test was used instead.

7.4 Results

16 male and 2 female individuals with PAD-IC took part in the study and walked in their self-selected speed wearing the C3C and control shoe. Participant characteristics are outlined in 7.1 table below.

Table 7.1: Participant demographics

Gender	16 male 2 female
Height (m)	1.69 (0.07)
Weight (Kg)	79.7 (13.12)
Age	72.3 (7.94)
Speed (m/s)	C3C shoe 1.09 (0.13) control shoe 1.11 (0.13)
Co-morbidities	Diabetes(1) COPD(1) poor eyesight (2)

Outdoor inclined walkway

No significant differences in peak muscle activity of the tibialis anterior, medial gastrocnemius, lateral gastrocnemius or soleus were identified walking up and

down the inclined outdoor walkway with the C3C shoe compared to the control shoe (tables 7.2-7.3).

Table 7.2: Average peak EMG for the tibialis anterior, medial gastrocnemius, lateral gastrocnemius and soleus muscles, while walking up the outdoor inclined walkway in the C3C and control shoe.

Up inclined walkway	Tibialis Anterior	Medial Gastrocnemius	Lateral Gastrocnemius	Soleus
C3C	3.11(0.72)	3.44(1.05)	3.40(1.17)	3.15(0.58)
Control	3.18(0.38)	3.73(0.87)	3.84(1.09)	3.16(0.92)
p value	0.845	0.306	0.157	0.913

Table 7.3: Average peak EMG for the tibialis anterior, medial gastrocnemius, lateral gastrocnemius and soleus muscles, while walking down the ramp in the C3C and control shoe.

Down inclined walkway	Tibialis Anterior	Medial Gastrocnemius	Lateral Gastrocnemius	Soleus
C3C	3.43(0.74)	3.37(1.00)	3.55(1.24)	2.91(0.52)
Control	3.36(0.53)	3.61(0.83)	3.36(0.99)	2.94(0.54)
p value	0.490	0.209	0.759	0.709

No significant difference was identified in the number step taken up and down the outdoor inclined walkway with the C3C compared to the control shoe. Participants took statistically significantly longer to walk up the outdoor inclined walkway compared to the control shoe. No significant difference in walking time was identified between the C3C and control shoe when walking down the outdoor inclined walkway (table 7.4).

Table 7.4: Average steps and time taken to walk up and down the ramp in the C3C and the control shoe.

	Steps		Time	
	Up inclined walkway	Down inclined walkway	Up inclined walkway	Down inclined walkway
C3C	77.3(6.68)	79.1(7.96)	43.53*(3.83)	43.6(4.46)
Control	76.2(8.13)	77.6(8.36)	41.6(4.85)	42.2(4.13)
p value	0.425	0.331	0.30	0.074

Stairs

No significant differences were identified differences in peak muscle activity of the tibialis anterior, medial gastrocnemius, lateral gastrocnemius or soleus during walking up the stairs with the C3C compared to the control shoe. When walking down the stairs, peak tibialis anterior activity was significantly increased when wearing the C3C compared to the control shoe. No significant differences were identified in peak medial, lateral gastrocnemius or soleus when walking down the stairs with the C3C compared to the control shoe (tables 7.5-7.6).

Table 7.5: Average peak EMG for the tibialis anterior, medial gastrocnemius, lateral gastrocnemius and soleus muscles, while walking up the stairs in the C3C and control shoe.

Up stairs	Tibialis Anterior	Medial Gastrocnemius	Lateral Gastrocnemius	Soleus
C3C	3.30(0.60)	3.99(0.88)	4.07(1.59)	3.28(1.15)
Control	3.24(0.45)	4.06(0.84)	4.09(1.25)	3.04(0.72)
p value	0.811	0.711	0.717	0.872

Table 7.6: Average peak EMG for the tibialis anterior, medial gastrocnemius, lateral gastrocnemius and soleus muscles, while walking down the stairs in the C3C and control shoe.

Down stairs	Tibialis Anterior	Medial Gastrocnemius	Lateral Gastrocnemius	Soleus
C3C	3.88(1.22)	3.53 (1.10)	3.08(1.18)	2.90(0.38)
Control	3.45(0.83)	3.09(0.62)	3.19(0.76)	2.85(0.54)
p value	0.020	0.056	0.420	0.711

Plantar pressures

Peak plantar pressure under the 2nd to 4th and 5th metatarsal head region was significantly reduced with the C3C compared to the control shoe. No other significant differences were identified (table 7.7).

Table 7.7: Peak pressures for the C3C and control shoe.

Peak pressure	C3C	Control	p value
Toes	262(68.5)	268.6 (66.9)	0.548
5 th metatarsal head	85.8(39.3)	122.7(59.5)	0.018
Heel	244.6(72.5)	245.3(66.7)	0.953
Midfoot	99.6(40.9)	89.5(33.6)	0.168
2 nd - 4 th metatarsal head	168.2(66.2)	207.4(71)	0.016
1 st metatarsal head	211.9(34.2)	217.2(61)	0.654
Hallux	202.9(76.4)	193.2(63.2)	0.433

6 minute walk test

No significant differences in peak muscle activity of the tibialis anterior, medial gastrocnemius, lateral gastrocnemius or soleus were identified while walking in the C3C and control shoe during the 6-minute walk test (table 7.8).

Thirteen of the 18 participants tested achieved and/or reported initial pain, ten participants achieved and/or reported moderate pain, ten participants achieved and/or reported intense pain and seven participants achieved and/or reported maximal pain, at which they stopped walking, during the 6-minute walk test. No significant differences were identified in pain free walking time, time to moderate, pain, time to intense pain and maximal walking time with the C3C shoe compared to the control shoe during the 6-minute walk test. The number of steps taken with each shoe and the average walking speed with each shoe did not differ significantly (table 7.9).

Table 7.8: Average peak EMG activity during the six-minute walk test for the tibialis anterior, medial gastrocnemius, lateral gastrocnemius and soleus muscles in the C3C and Control shoe.

6 min walk	Tibialis Anterior	Medial Gastrocnemius	Lateral Gastrocnemius	Soleus
C3C	3.16(0.57)	3.91(0.85)	4.10(1.41)	3.19(0.45)
Control	3.26(0.41)	3.75(0.90)	3.98(0.95)	3.07(0.45)
p value	0.594	0.285	0.555	0.065

Table 7.9: Average maximum time to pain and to each level of the pain scale until maximum walking time was reached and steps taken during the six-minute walk test with the C3C and control shoe.

6 min walk	Initial pain(s)	Moderate pain(s)	Intense pain(s)	Maximal pain(s)	Steps	Speed(m/s)
C3C	2m 33s	3m 16s	4m 16s	4m 30s	514(114.8)	1.09 (0.13)
Control	2m 35s	3m 31s	3m 53s	3m 44s	503(128.3)	1.11 (0.13)
p value	0.843	0.074	0.563	0.176	0.355	0.152

Questionnaire

The questions of the questionnaire used and average answers of participants are presented in the table below (table 7.10).

Table 7.10: Average answers to the questionnaire questions for the C3C and the control shoe.

	C3C
Compared to your everyday shoes how safe do you feel walking UP the staircase with the rocker shoes?	A bit less safe/mild fear of losing stability
Compared to your everyday shoes how safe do you feel walking DOWN the staircase with the rocker shoes?	A bit less safe/mild fear of losing stability
Compared to your everyday shoes how tiring did it feel to walk UP the staircase with the rocker shoes?	No noticeable difference
Compared to your everyday shoes how tiring did it feel to walk DOWN the staircase with the rocker shoes?	No noticeable difference
Compared to your everyday shoes how safe do you feel walking UP the ramp with the rocker shoes?	A bit less safe/mild fear of losing stability
Compared to your everyday shoes how safe do you feel walking DOWN the ramp with the rocker shoes?	No noticeable difference
Compared to your everyday shoes how tiring did it feel to walk UP the ramp with the rocker shoes?	No noticeable difference

Compared to your everyday shoes how tiring did it feel to walk DOWN the ramp with the rocker shoes?	No noticeable difference
How confident do you feel in completing this walk with your everyday shoe?	No noticeable difference
How confident do you feel in completing this walk with the rocker soled shoe?	Somewhat confident
Howe confident do you feel in completing this walk with the rocker soled shoe in comparison to your everyday shoe?	A bit more confident. I think I will stop fewer times.
How willing would you be to try the shoe if it were offered by the NHS?	I would try it.

7.5 Discussion

The aim of the study in the current chapter was to establish whether the C3C shoe was effective at significantly increasing pain-free walking distance and whether it was safe and comfortable to use in real-world like situations.

Suitability for individuals with diabetes

This preliminary pre-clinical study has shown that in terms of plantar pressure the C3C shoes are safe to use for individuals with PAD-IC who also suffer from diabetes. Individuals with diabetes are significantly more susceptible to foot ulceration due the reduced flow of blood to the foot, sensory neuropathy and plantar pressure. The combination of diabetes and independent peripheral arterial disease only magnifies the problem of insufficient blood flow which makes the importance of wound and ulcer prevention greater still. If the foot is neuropathic and the patient cannot feel pressure or pain in some or all of the regions of the sole, wounds can also remain unnoticed which further increases the possibility of infection and serious escalation of the problem. It was therefore very important that the C3C did not significantly increase plantar pressures during gait compared to a standard sole shoe and ideally that it keep pressures in high risk areas of the sole lower than 200kPa as recommended by Cavanagh and Buss (Cavanagh and Bus, 2011).

Waijman and Bus performed a study on 85 individuals with diabetes and a history of foot ulceration (Waijman and Bus, 2012). From his data the percentage prevalence of ulceration in different areas of the foot can be tentatively estimated (bearing in mind that the findings are from one study and a sample size of 85, which may not necessarily be representative of the wider population). This helps set some context for the interpretation of the changes in pressure in different areas, since changes in areas of greatest prevalence are a priority.

The C3C significantly reduced plantar pressures under the 2nd, 3rd and 4th and 5th metatarsal heads, areas that usually carry a 13% to 18% prevalence of ulceration in patients with diabetes and neuropathy (Waijman and Bus, 2012). Therefore, the shoe, in its current state, is capable of accommodating individuals with diabetic neuropathy and is in one respect better than an everyday shoe.

Plantar pressures under the hallux, 1st metatarsal head and phalanges did not change significantly compared to the everyday shoe. The lack of an increase in pressure is a positive outcome in that the shoes are as safe to use as any everyday shoe. However, further adaptations, such as adding pressure relieving insoles, can be made in the future to reduce pressures in these areas further. Such modifications could be warranted as both the control shoe and the C3C had maximum pressures in these regions higher than the recommended 200kPa threshold (Cavanagh & Buss, 2011). Both the hallux and first metatarsal head mean peak pressures remained within 11kPa of the threshold for the C3C. This indicates that the shoes do not greatly elevate risk at these areas (which have 18% and 27% ulceration prevalence, based on Waijman and Buss (2012)). However, pressures in both shoes for the toes averaged at 245kPa and 244kPa for the control shoe and C3C accordingly. Although this is a low ulcer prevalence area of 2% (Waijman and Bus, 2012) steps should still be taken to address these pressures.

Effects on mobility on angled walkway and stairs

There were few significant effects of the C3C in ambulation on slopes. This is a positive finding for stair and slope traverse, where it was important that the shape and weight of the shoe not affect these tasks negatively.

There were no statistically significant changes in muscle activity when walking up and down the outdoor inclined walkway. Previous research (Alexander and Schwameder, 2016) has shown that walking up an outdoor inclined walkway significantly increases gastrocnemius and soleus activity while reducing tibialis anterior activity, compared to walking on a flat surface. Conversely, walking down an outdoor inclined walkway reduces gastrocnemius activity but increases tibialis anterior and soleus activity (Alexander & Schwameder, 2016). Assuming the control shoe represents gait affected by the incline, the results indicate that the C3C shoe did not add further to these changes. The curved sole of the C3C could have caused a further increase in gastrocnemius and soleus activity while walking up the outdoor inclined walkway by inducing an external moment which would tend to rotate the sole of the shoe backwards toward the heel. The gastrocnemius and soleus would therefore have to produce a greater moment to counteract this moment. Conversely, when walking down the outdoor inclined walkway the curved sole could have induced a significantly greater external plantarflexion moment, creating imbalance and increasing the required force from the soleus and tibialis anterior. However, no such differences were identified. The lack of significant increase when walking up the inclined walkway may be due to the significant increase in walking time identified (by 1.93s; $p=0.030$). This would indicate that participants chose to walk slower to ensure that demand on the calf muscles remained low, inferring that, for the same walking speed, muscle effort would have been greater. However, pragmatically, the lack of significant increase in muscle activity demonstrates that their use would not increase the force required by these muscles on many urban routes, albeit small reductions in speed will have to be made up inclines.

Walking down the stairs significantly increased tibialis anterior muscle activity. Previous research has shown that, contrary to level walking, when walking down a flight of stairs the foot lands at the level of the toes and is lowered until the heel

makes contact (McFadyen and Winter, 1988). The increase in tibialis anterior activity seen in the current research, compared to the everyday shoe, may be due to both the shape and weight of the C3C. More specifically, due to the shoe being a rocker sole, landing with the centre of pressure at the level of the toes or metatarsal heads would have caused the limb to become unstable and the individual to fall forward. Therefore, the toes would have to be lifted up sufficiently before contact was made with the lower next step so that contact could be made via the midfoot, which offers a more stable base of support. Therefore, the tibialis anterior may have contacted more to lift the toes as the foot was lowered to the next step. This motion would not be intended to help toe clearance but instead to ensure that the tibia-foot relationship allowed the foot to land with the centre of pressure sufficiently posterior to the toes to ensure balance on the lower step. The increased weight of the shoe may have increased muscle activity further still. The increased activity of tibialis anterior might suggest increased demand for blood but occurred at a time of low loads, since the foot was off the ground.

Furthermore, while descending stairs, the tibialis anterior also contracts, in combination with the soleus, to invert the foot before it lands on the next step (Joseph and Watson, 1967, Benedetti et al., 2012). Once again this motion may have required greater muscle activity due to the weight of the shoe (turning force applied to heavier object). Future research could focus on the effect of the shoe weight to reduce the influence of this factor on swing phase effects observed in this study. This could ensure that tibialis anterior peak muscle activity, when walking down the stairs with the C3C, remains similar to an everyday shoe.

Walking up the stairs with the C3C, which requires the tibialis anterior to contract to ensure foot clearance, before placing the foot on the next higher step ((McFadyen and Winter, 1988) Joseph & Watson 1967; Benedetti et al. 2012), did not significantly increase tibialis anterior activity compared to the everyday shoe. This somewhat contradicts the notion that the additional shoe weight was an issue. In theory, the greater weight of the C3C could have caused an increase in tibialis anterior activity as it contracted to lift the toes clear of the edge of the next stair tread. The lack of significant increase may indicate that quadriceps activity

increased instead to sufficiently lift the knee and ensure clearance of the foot to the next higher step. Since the quadriceps are already active in lifting the foot to the next step, during this stage (McFadyen and Winter, 1988), only a small increase in quadriceps activity would be required to substitute clearance achieved by ankle dorsiflexion. This compensation may have been chosen because the tibialis anterior is a much smaller muscle, compared to the quadriceps and more likely to be structurally weakened by the disease. The quadriceps are larger proximal muscles, which are less often affected by claudication and are supplied with blood (and thereby oxygen) prior to the calf muscles.

However, using the quadriceps instead of the tibialis anterior is a less energy efficient mechanism for ensuring clearance of next higher step and increases the possibility of loss of balance (because it moves the centre of mass of the person higher on the vertical axis and further from the floor.) in a patient group (PAD-IC) which already suffers from reduced balance compared to healthy age matched counterparts (Gohil et al., 2013). A recent study investigating kinematics of people with PAD-IC during stair ascent did not identify an increase in hip flexion, which would have indicated a hip strategy, compared to controls (King et al., 2017). However, the footwear worn in that study are not mentioned and these were likely every-day running shoes or oxford style shoes, which would not have created as much a need for involvement of the hip. This is because the weight of such shoes is typically close to the weight of the control, oxford style shoe, used in the present study and therefore less than the weight of the C3C. Therefore, the tibialis anterior might have been able to produce the dorsiflexion moment required for clearance without the input of the quadriceps. The quadriceps EMG response to the footwear tested in this current study was not measured during the stair ascent tests. However, if the shoes are indeed causing an increase in quadriceps activity and alterations in kinematics which could impair balance, this would support the case to reduce the weight of the shoes.

Effects on pain-free and maximum walking distance and muscle activity a flat surface

Contrary to expectations, neither pain-free walking time (walking time to first instance of feeling pain) nor maximum walking time (walking time to the point where the pain is such that they must stop immediately) significantly increased when wearing the C3C shoes. Maximum pain-free walking distance, as number of steps taken, also did not significantly increase with the C3C shoe. This is a disappointing finding as walking distance is a key aim of management for people with PAD-IC. The above findings are consistent with the lack of decreases in peak muscle activity of tibialis anterior, medial or lateral gastrocnemius or soleus muscles. These findings demonstrate that the current rocker design is not capable of delivering a significant positive clinical effect under flat walking conditions.

It is important to note here that mean walking speed did not differ significantly between shoes during the 6 minute walk test. This is important because if speed had differed between conditions, the lack of significant increase in steps walked, during the 6 minute walk test, may have been due to an increase in force demand from the calf muscles to accommodate a greater speed. This is proven not to be the case.

Likewise, a difference in step length between the two shoes could have skewed results. However, the number of steps that participants took when walking up and down the 50-metre outdoor angled pathway, did not differ significantly between shoes. This is important because it indicates that participants took the same number of steps to cross the walkway with both shoes. Therefore, step length was the same for both the C3C and control shoe.

Although findings in the current study are not as encouraging as those in chapter 6, results do not directly contradict each other either. Specifically, although findings in chapter 6 indicated that the C3C reduces moment and power at the ankle in late stance, they did not indicate a significant reduction in peak calf muscle activity. This finding is mirrored by the EMG findings in the current study, as none of the four

muscles significantly changed their activity in the C3C shoe with respect to the control shoe. In chapter 6, it was the overall EMG activity of medial gastrocnemius, during stance, which was reduced for the C3C. The current study did not measure muscle work, which may have been reduced. This would highlight that it is not the overall activity of the muscles that affects walking distance but primarily the peak EMG activity during the gait cycle.

It remains the case however, that the reduction in moment, power and muscle work observed in chapter 6 under controlled conditions did not prove sufficient to cause a significant increase in either pain-free or maximum walking distance under less controlled conditions. The reason for the lack of significant change in walking distance may be rooted in the difference between statistical significance and clinical significance of an outcome. The fact that a difference in ankle moment in late stance is statistically significant between shoes does not mean that it will necessarily translate into a clinically significant increase in pain-free walking distance or reduction in muscle activity over a length of time for individuals with PAD-IC. This is because, even if the joint moments and power had been reduced it is unclear to what extent this translates into a meaningful reduction in oxygen demand, so that the oxygen supply is sufficient to prevent/postpone claudication pain.

This having been said, the findings of the study in chapter 6 showed that the addition of a solid AFO caused a significantly greater reduction in ankle power than the shoe alone. Rocker boots, which secure the ankle and foot in place, are commercially available and used by healthcare professionals to allow individuals with certain foot, ankle and shank fractures to ambulate freely, while ensuring that the affected bones remain secure and immobilised. This requires that the muscles moving these joints also remain at low levels of activity. Together these facts indicate that perhaps the level of effect on joint moment, power and muscle activity offered by a shoe plus ankle-foot orthotic and not that offered by the C3C alone, is necessary to induce a significant increase in PAD-IC walking distance (although this itself was not tested in this thesis). Consequently, perhaps a shoe modified into a

boot form that offers some of the additional mechanical effects of an AFO is required to impose even greater mechanical changes on the ankle and calf muscles.

The current study has shown that the C3C statistically insignificantly increases maximum walking distance by an average of 12 steps or approximately 4.5 meters. It is difficult to determine if there is any clinical significance to this increase, because there is a large range in the mobility of individuals with PAD-IC. For an individual with great mobility loss, who can barely make it across a ten-meter walk-way, a 4.5 meter increase can be seen as significant, in which case the clinical effect is high. For a person who can walk 20 minutes before they need to stop (maximum walking distance), 12 steps or 4.5 meters will have little practical value under real world conditions. Therefore, it may be that the shoes are an effective intervention only for individuals with very low mobility and still not sufficiently so to warrant their production. Further work would be required to understand the variation in effect on sub groups of people with different degrees of PAD-IC.

One previous study attempted to define the minimally important change (clinical significance threshold) in maximum walking distance in individuals with PAD-IC (van den Houten et al., 2016). The study used 102 individuals with PAD and symptomatic of IC (Fontaine stage II) and all had a maximum walking distance less than 500m, with mean walking distance of 280m. They used as an external anchor the findings of minimum important increase and decrease in walking impairment in a walking impairment questionnaire (WIQ) study performed by Conijn et al (2015) on 294 individuals with PAD-IC. The results indicated that people with PAD-IC consider an increase of at least 305 metres in maximum walking distance as the minimally important increase in walking distance. Also, that any increase in maximum walking distance, achieved through an exercise program or other intervention, that is less than 147 metres is actually perceived as an important decrease in walking distance by individuals with PAD-IC. Based on these outcomes the C3C did not prove capable of eliciting any clinically meaningful benefit in PAD-IC gait.

Patient preferences

The results of the questionnaire provide a first indication of patient preferences regarding the shoe and likelihood of using the shoes or not. On first acquaintance with wearing the C3C, participants did not fear falling, although a fear of losing stability up and down the outdoor inclined walkway was greater than their normal footwear. Most participants agreed that they felt no perceptible difference in calf muscle activity during the outdoor inclined walkway and stair tasks. This finding is mostly supported by EMG data with the exception of tibialis anterior muscle activity when walking down the stairs. However, this usefully illustrates the potential for a difference between quantitative data and qualitative data description real world perception.

As stated above, when wearing the C3C the majority of participants reported a mild fear of losing stability when walking up and down the outdoor inclined walkway. Since the shoes are curved they provide a smaller area of contact with the ground than normal footwear and thereby a smaller base of support, which could be perceived as offering less stability. The smaller base of support requires greater balance on the part of the patient. However, walking on the outdoor angled walkway was also the first task of the protocol and it is possible that the lack of substantial previous experience with the shoe combined with its irregular shape are the basis for the elevated concerns. Indeed, without being asked, most participants reported that they got used to the shoes as data collection progressed. Some participants mentioned this on the way to the second task (stairs) and others before starting the third task but, specific data on this was not collected. Interestingly when walking up and down the stairs most participants reported no perceived difference in stability/safety compared to the everyday shoe. This may indicate that after the first task (the outdoor inclined walkway) they felt more comfortable and confident in wearing the C3C.

Tasks were not randomised in the present study for 2 reasons. Firstly, it was deemed better to complete the 6 minute walk tests as the final tests as this was the most lengthy and potentially painful task and may have put participants off completing the rest of the study. Secondly, no randomisation of the first 3 tasks

could take place due to the walkway task being outdoor; making this a weather dependant task. It was decided that the walkway task would take place in any order that weather permitted. It conspired that there was no rain upon any of the participants arrival. The outdoor task was therefore always completed first to ensure that the experiment would not have to be cancelled due to rain. To reduce inconvenience to participants, the stair task was completed after the walkway task, leaving the plantar pressure task as third.

The majority of participants answered that they would try the shoe if it were offered by the NHS which indicates a willingness to conform to an intervention in the hope that it will increase their quality of life. However, not all participants were convinced that the C3C would help them walk longer without pain. Despite, on average, stating that they felt the C3C would help them to stop fewer times during a long walk, some participants reported that they felt the shoe would not make a difference, or would offer less benefit compared to their everyday shoe. This reflects the findings in maximum walking distance during the six-minute walk test as not all participants achieved greater distance compared to the everyday shoe.

Several factors may help explain a difference between quantitative data on the performance of walking and the perceptions of patients. Participants may have chosen to be “polite” is choosing more “positive” answers to the questions relating to shoe efficacy as it was very obvious which of the two shoes was experimental in nature. It may also be that far more acclimatisation time is required to alter gait and the associated physiological processes before a perceived benefit can be achieved. There are no data on how management of blood flow to the calf muscles responds to changes in joint moments, powers and calf EMG muscle activity data, and this would be a useful future study to help explain some of these results. In any case, the willingness of participants to try the shoes, if they were offered to them, indicates that there is a strong interest in such an intervention and warrants the continuation of footwear research for people with PAD-IC.

Limitations

Several participants made use of the stair rail when walking down the stairs with the C3C shoe. Use of handrail when ascending or descending stairs has been shown to alter gait kinematics and kinetics, and thereby possibly muscle activity (Reeves et al., 2008). However, the aim of the current study was not to assess the effect of the kinematic, kinetic or EMG for that matter effect of the C3C on stairs, but rather to assess whether the use of the C3C on stairs was at a first stage, considered safe enough by participants and whether it caused any adverse effects of muscle activity. When individuals make use of an intervention in the real world, this will not follow the strict rules and guidelines, set out and followed during a laboratory trial. Individuals of advanced age, such as those suffering from PAD-IC, are likely to make use of handrails on stairs or other walking aids to help them ambulate. It was therefore important to assess the effects of the C3C not free of external factors (i.e. use of handrail) but taking into account the manner in which individuals with PAD-IC would use the intervention in their everyday life.

This having been said, it is important to highlight that the increase in tibialis anterior activity identified when walking down the stairs with the C3C does not appear to be linked to the use of the handrail. More specifically, handrail use when descending stairs has been shown to increase ankle internal plantarflexion moment during propulsion to the next step (which is associated with gastrocnemius and soleus activity), and not dorsiflexion moment (which is associated with tibialis anterior activity). No significant increase in peak activity of the gastrocnemius or soleus was identified when descending the stairs with the C3C compared to the control shoe.

As mentioned in the previous chapter the C3C shoe is designed with much thicker sole than the control shoe, which is accompanied by an increased weight. Due to the upper of the shoe being low-cut, several participants commented at the beginning of the study that their heel tended to lift inside the shoe due to the weight of the sole. This was addressed by placing custom 7mm thick inserts on the inside of the shoe heel, made from low density VA, that acted as heel grips. It is possible that these grips were not completely effective in preventing the heel from

lifting but every attempt was made to ensure that this was the case. Furthermore, previous research on the effects of flip flops (which allow the heel to lift as there is no support at the heel) on muscle activity has indicated an increase in tibialis anterior activity during swing phase, which is postulated to be caused by an attempt of participants to grip the flip-flop with their foot (Price et al., 2014, Shroyer and Weimar, 2010). The present study did not investigate muscle activity in stance and swing separately but rather the overall peak activity throughout a series of gait cycles. No significant increase in tibialis anterior activity was seen with the C3C when performing walking tasks, and in fact, during the six-minute walk test, average peak tibialis anterior activity was non-significantly reduced compared to the control shoe. This supports the hypothesis that there was little to no heel slipping with the C3C shoe.

It is important to highlight that the participants who took part in the present study were different to the ones in the previous two chapters. Consequently, the lack of effect observed by the C3C on muscle activity and walking distance may be the result of using a different sample of individuals using the shoe. In a sense this may be seen as a limitation. However, the recruitment of new participants was deliberate. More specifically, due to the nature of the outcome measures in the previous studies, the inclusion criteria for participants was very strict, so as to ensure that any changes in gait kinematics, kinetics or EMG identified were true effects of the disease and not caused by extrinsic factors such as co-morbidities. However, the shoes are ultimately being developed as a management aid to assist the majority of individuals with PAD-IC and this is a very diverse cohort. It was therefore deemed important that since this study aimed to investigate the real-world effects of the shoes, it should be tested on a real-world set of patients. As a result, some participants in the current study were considerably more mobile, and some considerably less so than the ones recruited in the previous studies. This may have been part of the reason for the lack of accordance in results between the two studies. If indeed so, it strengthens the importance of conducting the present study because it highlights that under real world conditions and when used by the

average patient, management aides will perform very differently than in a meticulously planned laboratory environment.

Finally, although the present study sought to identify effects of the shoes in environments comparable to real world environments, the study was partly lab based and very structured. Therefore, the findings do not offer the same confidence as offering the shoes to participants as asking them to use them a specific amount of days during their daily lives, along with an activity monitor. Such data would indicate whether walking distances increased with the C3C shoes. However, the footwear researched in this thesis are experimental designs and can only be used in a lab environment for proof of concept research. It would only be legally possible for participants to use the shoes outside a lab setting if the shoes had received CE mark and regulatory approval, and in turn this is only possible if proof of concept is shown. Therefore, the structure of the study was necessary so that the shoes could receive CE mark in the future.

7.6 Conclusion

In conclusion, the current study proved that the kinetic and EMG effects of the C3C, identified in the previous chapter, did not elicit a significant clinical effect in terms of increased pain-free and absolute walking distance. Future research will need to focus on the reduction of the C3C shoe weight, the redistribution of the weight throughout the sole and the application of an appropriate level of restriction at the ankle joint, and relationship between biomechanical changes in the lower limb and management of blood flow to the lower limb.

Chapter 8. Review of findings, contribution of each study to research area and recommendations for future research

8.1 Review of Chapter 5

Chapter 5 investigated the effects of PAD-IC on gait and peak calf muscle activity. Eighteen individuals with PAD-IC and 18 healthy controls were admitted into the study. Participants walked at a self-selected speed along a straight path in the lab while temporal-spatial, kinematic, kinetic, ground reaction force and EMG data were collected. Findings indicated that individuals with PAD-IC walk with a reduced gait velocity and step length compared to healthy age-matched controls. Accounting for the effects of the difference in walking velocity, people with PAD-IC walk with a reduced ankle moment and ankle power in late stance which is mirrored by a reduced vertical and reduced anterior peak ground reaction force in late stance. Overall, they have a peak soleus activity which is 2.9 times their mean activity when healthy counterparts' peak activity is 3.6 times their mean. This tallies with the clinical picture of impaired effectiveness of the calf muscles due to limited blood supply that ultimately leads to calf pain.

People with PAD-IC also walk with a reduced knee and hip power absorption in early stance, mirrored by a reduced peak posterior ground reaction force in early stance and a reduced peak lateral ground reaction force.

The findings prove that many of the characteristics of PAD-IC gait identified in previous research are primarily speed related and not a direct reflection of muscle force capacity. However, the reduced speed is in itself a strong indicator that, due to degradation of the their muscles, individuals with PAD-IC, may not be capable of producing and maintaining the greater muscles forces required for a faster walking speed. Their fear of onset of claudication pain may also contribute to adoption a lower walking speed, since this will require lower forces from the calf muscles and in turn a smaller demand for oxygen. This allows them to walk further before claudication pain is felt, as less oxygen is demanded from the muscles to maintain a smaller speed. This could be a coping mechanism to seek to match demand to available oxygen supply by reducing walking speed.

The current study was the first study to present and discuss changes in peak muscle activity between individuals with PAD-IC and healthy age matched controls during

gait. Although Gommans et al investigated EMG activity in people with PAD-IC and healthy counterparts, they only reported duration of muscle activation in stance and not the maximum activity of calf muscles between groups (Gommans et al., 2016). The current research showed that peak soleus activity, with respect to mean activity, is significantly reduced compared to controls (including when the effects of reduced walking velocity are considered). This indicates a potential weakness of the soleus muscle. Both the gastrocnemius and soleus muscles produce force in late stance to allow the foot to push off the ground. However, the soleus muscle has a larger percentage of slow twitch muscle fibres than the gastrocnemius, and this percentage is further increased in individuals with PAD-IC. Therefore, the maximum contraction that the soleus can produce will be smaller than that of healthy counterparts. This finding supports the picture of PAD-IC gait in terms of kinetics and temporal spatial parameters, that indicate a gait pattern which aims to reduce muscle forces and thereby oxygen demand of the lower limb muscles.

The study findings suggest that footwear interventions designed to assist people with PAD-IC should not focus on reversing specific differences in limb kinetics that the disease has imposed on gait but rather focus on reducing the oxygen demand from the lower limb muscles. This means that a footwear intervention must manipulate external moments so that the degree of the force typically required by the calf muscles, can be reduced and thereby its need for oxygen can remain closer to the limited supply available. This should lead to an extended ability to walk pain free and at effective walking speed to maintain independent living.

8.2 Review of Chapter 6

Chapter 6 investigated the effects of a two curve rocker soled shoe (2C), and two versions of a three-curve rocker soled shoe (H3C) (C3C). These were tested in isolation and in combination with a rigid ankle foot orthotic. Their effects on gait kinematics, kinetics, ground reaction force, peak muscle activity and muscle work were investigated on 18 individuals with PAD-IC. Participants walked at a self-

selected speed, which was controlled to remain within $\pm 10\%$ of their mean for all shoe and shoe plus AFO conditions.

This was the first study to test the H3C shoe on kinetics and EMG of individuals with PAD-IC. It is also the first study which attempted to explain the function of a three curve rocker soled shoe using biomechanical formulae. Although this does not equate to the development of a biomechanical model for use, it provides a mathematical exploration of the mechanisms through which a rocker soled shoe might manipulate internal ankle moments and power and potentially muscle activity. These mechanisms may allow future research aimed at changing specific gait variables in PAD-IC, to design footwear based not solely on practical experience and footwear literature, but on a mathematical analysis of shoe effects.

The study findings indicated that a three curve rocker soled shoe can significantly reduce external ankle dorsiflexion moment and ankle power production in late stance, whilst increasing knee power absorption in early stance.

By adding a rigid AFO to the shoe, the ankle power in late stance was further significantly reduced and ankle power in early stance is also reduced. However the orthotic also causes a significant increase in external knee flexion moment in early stance and external knee extension moment in late stance, as well as a significant increase in knee power generation in mid to late stance. Use of the AFO with the two versions of the three curves soles increased moments and power at the knee throughout stance. The increase in external knee moments can increase the oxygen required by the thigh muscles proximally, thereby reducing the available supply to the calf muscles distally and is therefore an unwanted effect.

The findings therefore indicate that the C3C and H3C reduce the internal demand moment at the ankle in late stance, without causing unwanted effects proximally, and should thereby reduce the force required by the calf muscles. This should thereafter reduce local oxygen demand from the calf muscles. The C3C also significantly reduced the total EMG activity of the medial gastrocnemius throughout stance, compared to the control shoe. The significant reductions identified within the study support the biomechanical explanation of the shoe

design and indicate that the C3C shoes may be capable of eliciting a significant increase in pain-free and maximum walking distance in individuals with PAD-IC.

8.3 Review of Chapter 7

Chapter 7 investigated the effects of the C3C on gait under circumstances that are closer to those encountered in the real world and served as a pre-clinical study. The effects of the C3C on peak muscle activity when walking up and down an inclined outdoor walkway, up and down a flight of stairs and while completing a six minute walk test were investigated in 18 individuals with PAD-IC. Steps and time taken to pain free and maximum walking distance were collected to determine whether the reduction in ankle moment and power observed in study two was great enough to cause a significant increase in walking distance in individuals with PAD-IC. Finally, since many individuals who suffer from PAD-IC also suffer from diabetes and diabetic neuropathy, which make them susceptible to plantar ulcers, plantar pressure was also measured under the feet.

The study results showed that plantar pressures when walking with the C3C remained below the threshold value of 200kPa for the areas of the plantar surface of the foot associated with the highest risk of ulceration (1st to 5th metatarsal head). The C3C footwear therefore poses no specific risk to feet affected by diabetes. The shoes also did not cause a significant increase in medial and lateral gastrocnemius or soleus activity when walking up and down the inclined walk way and the staircase.

However, the shoe did not cause a significant increase in either pain-free or maximum walking distance of individuals with PAD-IC nor did it significantly decrease peak muscle activity of the tibialis anterior, medial, lateral gastrocnemius or soleus muscles.

The lack of significant effect on walking parameters may indicate that the reduction in late stance moment and power caused by the shoe is not sufficient to produce a significant decrease in calf muscle forces, to an extent where the oxygen demand

is matched with the supply. This in turn indicates that further manipulation of the shoe sole is required and supports the addition of an ankle foot orthotic that can elicit a degree of the reduction in ankle power identified in study 2 (but without the increases in knee moment and power also observed when wearing an AFO).

In summary, the current thesis links the physiological effects of PAD-IC (muscle changes and oxygen availability) to its effects in gait and muscle activity (chapter 5). In turn these are linked to the objective of an effective intervention, which is to reduce the force required by the calf muscles by manipulating the external ground reaction forces and the subsequent external joint moments and powers, and the corresponding internal forces and moments created by muscles. This objective is linked to mathematical model that explains the hypothetical effect of rocker soled footwear on gait, which were in turn supported by the experimental kinetic and EMG effects of the rocker sole footwear on individuals with PAD-IC in study 6. Finally, these were linked to real world effects and whether the change in kinetics relates to changes that are clinically significant (chapter 7).

8.4 Future research

For the purpose of creating a more effective shoe design, with the potential to both statistically and clinically increase pain-free and maximum walking distance in individuals with PAD-IC, modifications to the current C3C design will need to be considered.

More specifically, the study outlined in chapter 6 showed that the addition of a solid ankle foot orthotic substantially decreases both moment and power at the ankle in late stance for individuals with PAD-IC. However, the AFO was poorly tolerated by the patients. Therefore, future studies will need to examine the effect of adding a more pliable ankle-foot orthotic, than the one used in the current research, to the C3C shoe, to further reduce the demand moment and power at the ankle while maintaining oxygen demand at the thigh low.

Furthermore, future research should consider varying the shoe density in different regions of the shoe, so that their centre of mass is located closer to the ankle joint. The current rocker soled shoes have a uniform density and when standing upright cause a small plantarflexion moment which the individuals wearing them need to counteract. This may significantly increase gastrocnemius and soleus muscle activity while standing and may decrease comfort, parameters that were not tested in the present research. If the shoe was weighted so that the centre of mass (when accounting for the weight of the foot) was just in front of the ankle joint, this would ensure that no large moments are created when standing, while still creating a plantarflexion moment as the foot moves into mid-stance and the centre of mass of the body moves in front of the centre of mass of the shoe.

The mass distribution and angular acceleration of the shoe could be manipulated by designing a sole, which is separated into sections internally, each of which is partly filled with a sand-like compound (fig 8.1). The shift of the sand-like compound from the posterior of the shoe to the anterior of the shoe as the foot moves from heel contact to toe off, will continuously shift the centre of mass forward along the length of the shoe-foot. Since the equilibrium position continues to move forward, the shoe-foot will continue to rotate to reach this position. This should further reduce the internal ankle moment from mid-stance to late stance, which should in turn further reduce muscle activity and by consequence, oxygen demand from the calf muscles.

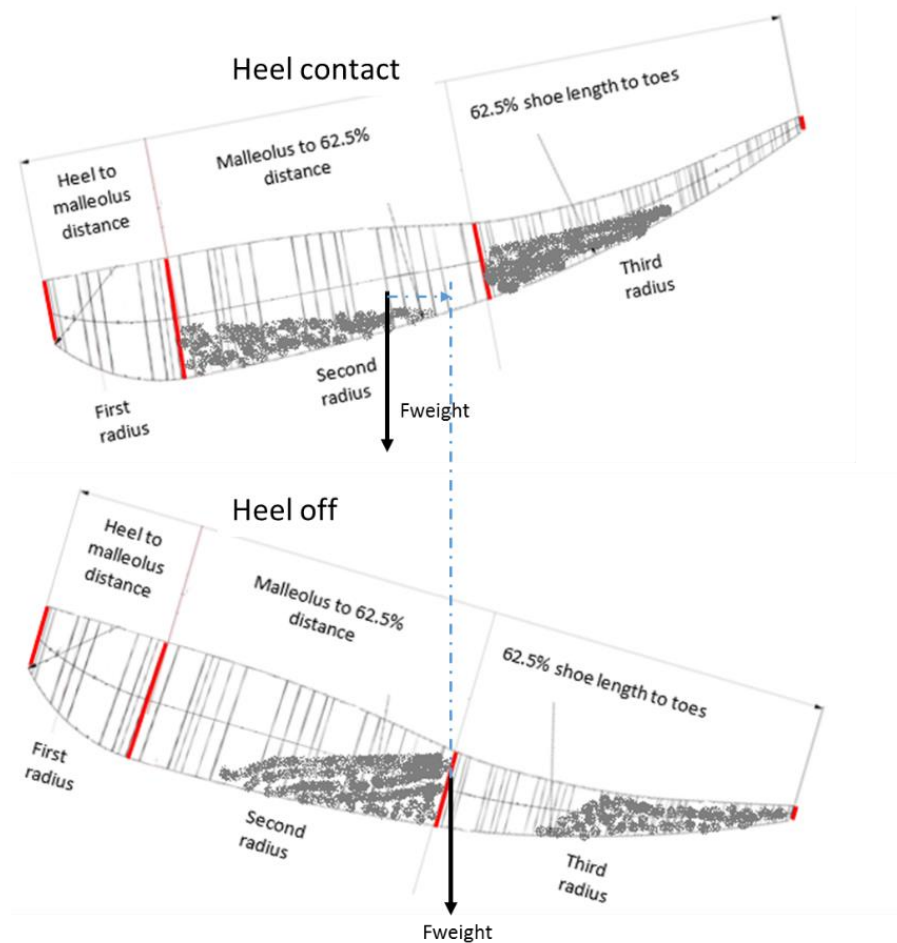


Figure 8.1: Image depicting the effect of a sand-like component on centre of mass and thereby weight position on the shoe in early and late stance.

Finally, the third arc of the C3C shoe (related to the distance from the ground to the knee joint centre) may be manipulated to increase the effectiveness of the shoe, by decreasing its radius to further reduce the plantarflexion demand moment in late stance. Study 6 indicated that a 3 cm reduction in arc radius is not sufficient to cause a significant effect on kinetics. Therefore, the effects of larger reductions in radius would need to be tested.

The alterations outlined above, used in combination with one another, may increase the effectiveness of the footwear in increasing pain-free walking distance in individuals with PAD-IC.

As a concluding remark, it should be remembered that any intervention that aims to reduce the muscle activity of individuals with PAD-IC during gait will be a form of management but not treatment. Peripheral arterial disease can reduce life expectancy and cause patients to lose limbs. The progress can only be improved if patients change their way of life and conform to exercise schedules to encourage growth of peripheral circulation. In this sense, an intervention that decreases calf muscle activity and thereby the formation of these additional arteries can be seen as not helpful or potentially contraindicated. However, it must be remembered that these shoes are targeted toward individuals who have lost a significant amount of their walking distance with debilitating effects on their mobility and quality of life. Therefore, any shoe that allows them to increase their pain-free walking distance should indeed not reduce their overall muscle activity, but simply allow them to apply their muscles over a longer period of time. In other words, it is anticipated that individuals will still reach their maximum walking distance, thereby not reducing their level of exercise, but do so over a longer distance. It follows that patients should understand that the shoes aim to increase their quality of life but not the outlook of their PAD condition.

Chapter 9. Conclusion

The current thesis has added to the literature on PAD-IC gait, highlighting the importance of accounting for differences in walking speed and offering the first comparison of peak EMG calf muscle activity during gait between individuals with PAD-IC and healthy age-matched controls.

This thesis is also the first to identify the biomechanical relationships that affect ankle joint kinetics when wearing a rocker soled shoe and these can be used as a platform from which to develop the shoe design. It was proven that a three curve rocker soled shoe design is capable of reducing moment and power at the ankle of individuals with PAD-IC in late stance and the work of the medial gastrocnemius muscle. The addition of an AFO to rocker soled shoes further substantially reduces moments and power production at the ankle, whilst also reducing activity of the tibialis anterior muscle. However, the potential increase in thigh muscle forces and the reduced patient compliance with such devices, reduce the effectiveness of the AFO as an additional intervention.

Finally the thesis demonstrated that statistically significant kinetic findings within a laboratory do not necessarily translate to a statistically, or clinically significant effect in the real world. The propositions for future research, based on the findings of this thesis, may allow for the development of a rocker soled shoe or rocker soled shoe plus AFO intervention that is capable of clinically increasing the pain-free walking distance of individuals with PAD-IC. Alternatively, future research may prove that despite the ability of rocker soles to manipulate kinetics and muscle activity around the ankle and calf, the scale of the clinical effect of this manipulation does not warrant use of shoes for this purpose.

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APPENDIX A: Repeatability study Pedar

Repeatability of Novel Pedar®– for measuring plantar pressures

There is a high percentage of individuals with diabetes mellitus who also suffer from PAD-IC (Tresierra-Ayala & García Rojas., 2017), some of whom have neuropathy in their feet. Therefore, any footwear intervention which aims to assist individuals with PAD-IC must be safe for use by individuals with diabetes and diabetic neuropathy. Consequently, the current research used Pedar® version I (Novel GmbH, Munich, Germany) to detect plantar pressures and conducted a repeatability assessment with Pedar as part of pilot studies prior to data collection with individuals with PAD-IC. This was to ensure that peak pressures were repeatable in both the control shoe and a rocker soled shoe. Since the latter is not a commonly used type of shoe, it was possible that the perturbation caused by the shoe, rocking through stance, could reduce the repeatability of the data. Plantar pressure repeatability was conducted separately from gait and EMG repeatability because it took place later within the research, before the initiation of the study in chapter 7.

A.1 Introduction

Pressures at the plantar surface of the foot can be measured using insoles incorporating load sensors. These insoles are placed inside the pair of shoes under examination and indicate the pressures on the plantar surface during standing and gait. A commonly used system is Pedar® (Novel GmbH, Munich, Germany). Repeatability of the Pedar system has been previously assessed by Ramanathan et al (Ramanathan et al., 2010). The study documented plantar pressures with Pedar X on 27 healthy male volunteers (ages 20 – 44) during two data collection sessions one week apart. The study used a sampling rate of 50Hz and analysed the foot into 10 areas: heel, midfoot, first metatarsal head, second to fourth metatarsal head, third metatarsal head, fourth metatarsal head, fifth metatarsal head, hallux, second toe and third to fifth toe, according to Bontrager (1997). Repeatability was measured using the coefficient of variance, which measures the error in relation to the mean. The lower the value, the better the repeatability. Ramanathan et al

(2010) reported that highest repeatability was found under the heel (7.7), followed by the 1st-4th metatarsal head regions, while the 3rd-5th toes (20.9) were the least repeatable.

A.2 Methods

Five healthy individuals, aged 20 to 30, with no injury to their legs or spine, were recruited from within the staff and post graduate student population at the University of Salford via email, (through the school secretary). This contained the information sheet and invitation letter to the study. Individuals who were interested could respond to the email to ask further questions and if willing to set a date for the study. Individuals who were not interested in taking part could simply ignore the email. Testing was conducted in the clinical gait laboratory at The University of Salford.

Participants who agreed to take part were asked to walk consecutively for six times along an eight-metre walkway, with a control shoe (Oxford style), used in the previous reliability study (4.2) and throughout the current research, and the three curve rocker soled shoe (C3C) outlined in chapter 6. Both shoes were standardised and provided in sizes 37-41 for women and 40-44 for men. The order in which participants wore the shoes was pre-randomised using an online randomisation tool (www.randomizer.org). Before completing walking trials the Pedar insoles were placed in each shoe, between the shoe insole and the foot. The insoles were attached to a transmitter box by being plugged into wires (these were secured with bandages to the limbs of the individuals to avoid tripping or loss of connection). The transmitter, along with its power battery were secured on a neoprene belt which was worn around the participants' waist secured with Velcro. Pedar ® (Novel GmbH, Munich, Germany) software was used to capture the data collected by the insoles.

When the foot is placed into the shoe and secured with the strap, a small level of pressure is already present and identifiable by the Pedar insoles. These pressures are a baseline noise and need to be discounted. In order to do this, before data

collection with each shoe and while participants were seated, they were asked to raise one leg at a time and keep it in the air for a few seconds, as the Pedar software recorded the baseline pressures present within the shoe, so as to discount them from subsequent data. The seated position of participants ensured that they did not lose their balance, trying to balance on one leg, which would have led to placing their foot back down while baseline noise was being discounted.

Afterwards participants were asked to complete six sequential walks along an eight metre walkway at their comfortable speed. Speed was monitored with the use of timing gates. Participants were free to walk at different speeds for each shoe, as long as that speed was kept consistent for that shoe type throughout the session and between sessions. In order to ensure this, prior to all data collection, participants were asked to walk five times with each shoe along the walk way. Their mean speed, in each shoe, was calculated and from that a window of $\pm 5\%$ to which they would need to adhere during data collection (both mean speed and time window were calculated using a Matlab script) was also calculated. If participants' speed fell outside this window they were made aware and asked to "walk a bit more quickly" or "a bit more slowly" during the next walk accordingly. Walks that were performed outside the speed window were discarded.

All data was output into ascii file format and imported to Matlab for further processing. Using a script written by a research fellow, the sensors of the Pedar insole were grouped into sections, known as masks. Each mask represented a part of the foot sole (fig 4.6). The masks used were: hallux, 2nd to 5th toe, 1st metatarsal head, 2nd to 4th metatarsal head, 5th metatarsal head and rearfoot and were defined according to Bontrager (1997). Maximum plantar pressure in each mask for each participant throughout the walk was computed for each shoe condition. This was accomplished by the Matlab script finding the peak pressure in every sensor of each mask and choosing the peak of peaks for every step. These were then averaged

over all steps taken. The data for each participant were exported to excel and collated for all participants.

A.3 Statistical Analysis

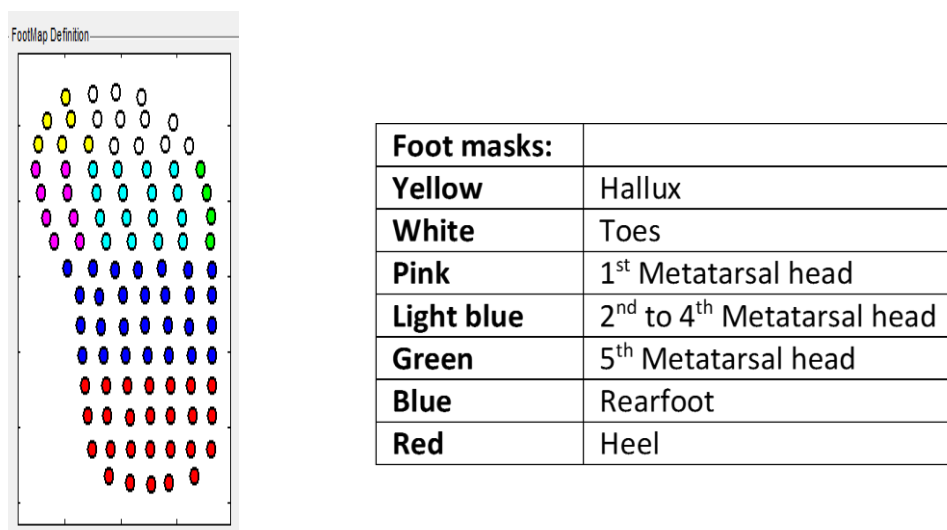


Figure 1: Image of Pedar insole sensors on the left foot, as represented in Matlab script. Each colour represents an anatomical depiction of the foot and a foot mask. Mask colours and respective anatomical regions are outlined in the table on the right.

Repeatability was measured, by computing intra-class correlation coefficients (ICC), pooled standard error of the mean (SEM) and minimal detectable difference (MDD). Both the control shoe and the rocker soled shoe (C3C), which chapter 6 will indicate as the most effective and will be used in the chapter 7, were assessed. ICC values were computed using SPSS software (Version 23, IBM Corporation). The values were interpreted according to the grading system outlined by Coppieters. The SEM and MDD were computed using the following formulas: $SEM = SD \text{ (pooled)} * \sqrt{1 - ICC}$, $MDD = 1.96 * SEM * 1.4142$.

A.4 Results

ICC values for the control shoe were excellent (Coppieters et al, 2002) for the 2nd to 4th metatarsal head region and the first metatarsal head region (Coppieters et al). Values were good for the toe, 5th metatarsal head and rearfoot regions and fair for

the heel and hallux regions (Coppieters et al., 2002). For the C3C results were excellent for the toe, heel, rearfoot, first metatarsal head and hallux regions and good for the 2nd to 4th metatarsal head and 5th metatarsal head region (Coppieters et al., 2002)(table 4.6). The standard error of the mean and minimal detectable difference were high for the control shoe in the toes and heel but acceptable in the remaining regions of the foot for the control shoe (4.7, 4.8). The SEM and MDD for the C3C shoe was highest at the toe region but considerably less so than for the control shoe (4.7, 4.9).

Table 1: Intra-class correlation coefficient (ICC) for control shoe and C3C shoe for the right leg and left leg.

ICC	Control Shoe R	Control Shoe L	C3C Shoe R	C3C Shoe L
Toes	0.87	0.94	0.9	0.95
Heel	0.65	0.82	0.92	0.91
5 th metatarsal head	0.86	0.81	0.7	0.86
Rearfoot	0.87	0.71	0.91	0.87
2 nd to 4 th metatarsal head	0.92	0.87	0.87	0.96
1 st metatarsal head	0.99	0.99	0.96	0.88
Hallux	0.5	0.96	0.91	0.88

Table 2: Standard error of mean (SEM) and minimal detectable difference (MDD) (in KPa) control shoe

Control Shoe	SEM Right	SEM left	MDD Right	MDD left
Toes	45.2	11.8	125.2	32.71
Heel	78.8	12.74	218.4	35.31
5 th metatarsal head	9.6	11.3	26.7	31.32
Rearfoot	5.4	7.48	14.9	20.73
2 nd to 4 th metatarsal head	10.9	8.95	30.3	24.81
1 st metatarsal head	11.8	8.63	32.6	23.92
Hallux	19.8	7.24	55.3	20.07

Table 3: Standard error of mean (SEM) and minimal detectable difference (MDD) (in KPa) control shoe

C3C Shoe	SEM Right	SEM Left	MDD Right	MDD Left
Toes	24.5	12.56	68	34.81
Heel	12.5	12.47	34.6	34.56
5th metatarsal head	11.7	12.01	32.3	33.29
Rearfoot	6.8	3.86	18.9	10.70
2nd to 4th metatarsal head	13.6	6.02	37.7	16.89
1st metatarsal head	20.9	13.26	57.8	36.75
Hallux	22.5	8.70	62.4	24.11

A.5 Discussion/Conclusion:

The current research will use plantar pressures to determine the safety or possible risk of using a specific rocker soled shoe by people with PAD-IC who may also suffer from diabetes and diabetic neuropathy. These individuals present with high pressures at the plantar surface of their feet. If footwear do not allow for these pressures to remain below a certain threshold, the risk for ulceration in these areas is high.

Repeatability, as examined from the intra-class correlation coefficient, was good to excellent in both shoes in the under the 1st to 4th metatarsal head which have a risk of ulceration of 17%-27 (Waaijman et al., 2012). However, repeatability was poor for the hallux of the control shoe, a site where incidence of ulceration is relatively high at 18% (Waaijman et al., 2012). Therefore, the interpretation of findings in chapter 7 will need to be made with caution with respect to the hallux for the control shoe.

Standard error of the mean was high for the toes and heel of the control shoe and for the toes of the C3C. The standard error is one of the factors which affects the ICC and it has already been acknowledged, in the results section, that repeatability is low in these regions. However, this research will focus mostly on the peak pressures of the rocker soled shoe and on how they relate to the pressure threshold for safety against ulceration. Since ICC and SEM are only high for the toes, a region

that has a low probability of being affected, the findings indicate that the use of Pedar to determine peak pressures in high risk areas of the foot, primarily with the C3C, but also with the control shoe, is acceptable. Minimum detectable differences will be advised during the interpretation of chapter 7 results to inform as to the clinical significance of changes in pressure.

APENDIX B: Questionnaire for chapter 6

ID number:

Shoe type:

How stable do you feel when standing in this shoe compared to your normal footwear?

1 2 3 4 5 (circle most appropriate)

Very unsteady

No feeling of
unsteadiness

How stable do you feel when walking along a smooth surface with this shoe compared to your normal foot wear?

1 2 3 4 5 (circle most appropriate)

Very unsteady

No feeling of
imbalance

Do you feel unsteady:

Side to side

YES

☐

NO

☐

If Yes:

1 2 3 4 5 (circle most appropriate)

Very unsteady

No feeling of
imbalance

Back to forward

YES

☐

NO

☐

If Yes:

1 2 3 4 5 (circle most appropriate)

Very unsteady

No feeling of
imbalance

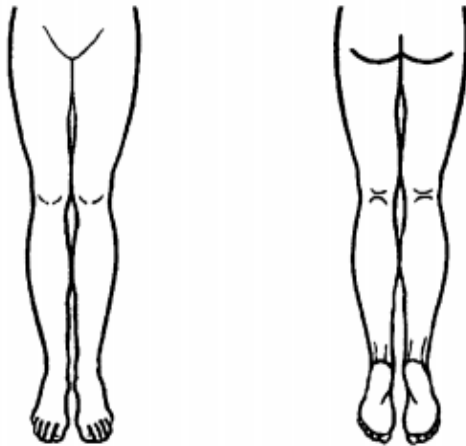
Do you feel your leg muscles are working more or less when wearing this shoe?

More ☐

Less ☐

No noticeable difference ☐

Please specify one or two areas of most noticeable difference in the picture below by marking with an M for more and L for less (if no difference leave blank).



Notwithstanding appearance would you feel comfortable walking in this shoe during your daily activities?

Yes ☐

No ☐